IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA
MARTINSBURG DIVISION

JEFFERSON COUNTY COMMISSION,

Plaintiff,

V.

Civil Action No. 3:17-cv-144 (Groh)

PURDUE PHARMACEUTICAL PRODUCTS, LP, PURDUE PHARMA, LP, THE PURDUE FREDERICK COMPANY, INC., ACTAVIS PHARMA, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, CEPHALON, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, TEVA PHARMACEUTICALS, INC., TEVA SALES AND MARKETING, INC., MALLINCKRODT ENTERPRISES, LLC, MALLINCKRODT ENTERPRISES HOLDINGS, INC., AMERISOURCEBERGEN DRUG CORP., CARDINAL HEALTH, INC., CARDINAL HEALTH PHARMACY SERVICES, LLC, CVS INDIANA, LLC, ENDO PHARMACEUTICALS, INC., ENDO HEALTH SOLUTIONS, INC., H.D. SMITH WHOLESALE DRUG CO., MCKESSON CORP., RITE AID OF MARYLAND, INC., WAL-MART STORES EAST, LP, and WALGREEN CO.

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff, JEFFERSON COUNTY COMMISSION, brings this civil action to eliminate the hazard to public health and safety and to abate the public nuisance caused

by the opioid epidemic in Jefferson County, West Virginia, and to recoup monies it has spent because of defendants' false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of the Defendants' intentional and/or unlawful actions and omissions. In support, of its Complaint, Plaintiff alleges as follows:

I. PRELIMINARY STATEMENT

1. Jefferson County, West Virginia, like much of the United States, is in the middle of an epidemic of prescription opioid drug abuse, an epidemic that threatens the health and well-being of not only the individuals who abuse opioid drugs, but of the families and communities of those individuals. In fact, the abuse of prescription opioid drugs is so pervasive in this country, that on October 26, 2017, President Donald J. Trump proclaimed the epidemic level abuse of prescription opioid drugs a National Public Health Emergency. Notably, West Virginia was one of only two states mentioned by name in Trump's October 26, 2017, speech.

2. Prescription opioid analgesics are narcotics. They are derived from and possess properties similar to opium and heroin and they are regulated as controlled substances.[1]

[1] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 829. Opioids that have been categorized as Schedule II drugs include morphine (Avinza, Embeda, Kadian, MS Contin), fentanyl (Duragesic, Fentora), heroin, methadone, oxycodone (OxyContin, Percocet, Percodan, Tylox), oxymorphone (Opana), and hydromorphone (Dillaudid, Palladone).

While opioids can dampen the perception of pain, they can also create an addictive, euphoric high. At higher doses, opioids slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few opioid therapies will experience often prolonged withdrawal symptoms – including severe anxiety, nausea, headaches, tremors, delirium and pain – if opioid use is delayed or discontinued. When using opioids, continuously, patients grow tolerant to their analgesic effects – requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

3. The opioid crisis is the result of the combined acts and omissions of opioid manufacturers and wholesale distributors who placed sales and profits over the health and welfare of the general public.

4. By the 1990's the manufacturers of prescription opioids (the "Manufacturer Defendants") had developed the ability to cheaply produce massive quantities of opioid painkillers, but the market for these drugs was small. Originally, physicians prescribed opioids sparingly as an effective treatment for short-term post-surgical care and palliative end-of life care. The Defendant Manufacturers and the medical community knew – and had known for years – that opioids were too addictive and too debilitating for long-term use for chronic, non-cancer pain (pain lasting three months or longer). Particularly

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Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812. Schedule III drugs may not be dispensed without a written or oral prescription or be refilled more than 5 times. 21 U.S.C. § 829. Some opioids had been categorized as Schedule III drugs, including forms of hydrocodone and codeine combined with other drugs, like acetaminophen. However, in October 2013, the FDA, following the recommendation of its advisory panel, reclassified all medications that contain hydrocodone from Schedule III to Schedule II.

because their effectiveness waned with prolonged use and because of the substantial risk of significant side effects and addiction, especially with high-dose use.[2] Consequently, the market for prescription opioids was sharply restricted.

5. The Manufacturer Defendants knew that to expand their market and profits, they needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions, like back pain, migraines, and arthritis. The Manufacturer Defendants spent millions of dollars funding, assisting, and encouraging doctors and front groups that would pioneer a new, far broader market for the potent and highly addictive opioids – the chronic pain market. The Manufacturer Defendants worked together to cultivate a narrative that pain was undertreated and that pain treatment should be a higher priority for health care providers. This effort paved the way for increased prescribing of opioids for chronic pain. The Manufacturer Defendants' promotional efforts dovetailed with this narrative, as the Manufacturer Defendants began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, the Manufacturer Defendants misrepresented to prescribers and consumers the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use. The Manufacturer Defendants even deceptively marketed the drugs for indications and benefits that were prohibited by the drugs' labels. There was and is no

[2] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Research & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds.).

reliable scientific evidence supporting the Manufacturer Defendants' marketing claims, and there is a wealth of scientific evidence to the contrary.

6. The Manufacturer Defendants successfully effected a sea-change in doctors' and the public's cautious approach to the prescription and use of opioid medications. From the 1990's to 2011, prescriptions of opioid drugs more than doubled in the United States. During the same time period, opioid prescriptions increased some 31% from approximately 1.6 million to approximately 2.2 million. According to a U.S. Department of Health and Human Services Fact Sheet, "[i]n 2014, more than 240 million prescriptions were written for prescription opioids, which is more than enough to give every American adult their own bottle of pills. Opioids – once a niche drug – are now the most prescribed class of drugs – more than blood pressure, cholesterol, or anxiety medications."[3]

7. While Americans represent only 4.6% of the world's population, they have consumed 80% of the opioids supplied around the worlds and 99% of the global hydrocodone supply.[4] Roughly 87% of these prescriptions are for chronic opioid therapy[5] – a prescribing practice doctors previously considered not just ineffective, but even reckless given the substantial risk of addiction chronic opioid use creates.

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[3] U.S. Department of Health and Human Services, *The Opiod Epidemic by the Numbers,* https://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf

[4] Laxmaiah Manchikanti et al., *Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective,* 13 Pain Physician, 401-435 (2010).

[5] Michael Von Korff, Group Health Res. Ist., "The Epidemiology of Use of Analgesics for Chronic Pain," Presentation to the FDA (2012), *available at,* http://www.fda.gov/downloads/Drugs/NewsEvents/UCM308128.pdf.

8. It was the Manufacturer Defendants' marketing and sales – not any medical breakthrough, that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The results have been catastrophic. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the nation has been swept up in opioid-induced "public health epidemic."

9. The numbers tell a harrowing story about the success of the Manufacturer Defendants deliberately misleading campaign. Prescription opioid use contributed to 16,651 overdose deaths nationally in 2010 – more than twice as many deaths as heroin and cocaine combined and surpassing motor vehicle accidents as a cause of death. For every death, more than 30 individuals are treated in the emergency room. Between 2007 and 2012, Jefferson County saw 57 total opioid-related overdoses with an overdose rate of 10.6 per 10,000 people.[6] According to the CDC, more than 12 million Americans aged 12 or older used prescription painkillers without a prescription in 2014, and adolescents are abusing opioids in alarming numbers.

10. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors or from the secondary criminal market, and a pipeline of drugs that can be diverted to supply them. Sixty percent of opioid abusers report that their drug use started with prescriptions.[7]

[6] West Virginia Department of Health and Human Resources, West Virginia Drug Overdose Deaths Historical Overview 2001-2015, p. 7.
[7] Nathaniel Katz, *Opioids After Thousands of Years, Still Getting to Know You*, 23 The Clinical Journal of Pain, 303-306 (2007).

11. The diversion of opioid drugs was made possible by the negligent and illegal actions of the Distributor Defendants, wholesale drug distributors, and sellers who bring prescription opioids into West Virginia and Jefferson County.

12. In 1970, Congress devised a "closed chain of distribution specifically designed to prevent the diversion of legally produced controlled substances into the illicit market." *Gonzales v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827; 880; H.R. Rep. No. 91-1444; 1970 U.S.C.C.A.N. 4566, 4572 (Sept 10, 1970). This closed system imposes specific duties upon wholesale distributors to monitor, identify, halt, and report "suspicious orders of controlled substances." 21 C.F.R. § 1301.74; *Masters Pharm. Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

13. As discussed *infra*, it has become abundantly clear that the Distributor Defendants failed to comply with the applicable laws. This failure is directly responsible for the volume of prescription opioids plaguing our community.

14. Many abusers of prescription opioids also abuse illegal drugs like heroin. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use. Heroin produces a high similar to that of prescription opioids, but is often cheaper. While a single opioid pill may cost $10 - $15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. In West Virginia, heroin-related overdose deaths (523) have been second only to oxycodone-related deaths (582) in the past three years.[8]

[8] West Virginia Department of Health and Human Resources, West Virginia Drug Overdose Deaths Historical Overview 2001-2015, p. 8.

15. From 2012 through 2015, total deaths resulting from opioid use in the population aged 45 – 54 was 609, with 258 of those caused by oxycodone.[9] It is hard to imagine the powerful pull that would cause a law-abiding middle-aged person started on prescription opioids for a back injury to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

16. Dr. Robert DuPont, former director of the National Institute on Drug Abuse and the former White House drug czar states the opioids are more destructive than crack cocaine:

> [Opioid abuse] is building more slowly, but it's much larger. And the potential for death, in particular, is way beyond anything we saw then . . . [F]or pain medicine, a one-day dose can be sold on the black market for $100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.[10]

17. To shift medical convention and unleash this epidemic, Defendants engaged in a campaign of deception that: (1) misrepresented the efficacy of opioids, (2) trivialized or obscured their serious risks and adverse outcomes, (3) overstated their superiority compared with other treatments; (4) provided no limitation or oversight on the volume of prescription opioids available in a given community, and (5) in fact, encouraged use of prescription opioids that did not conform to the drugs' authorized uses. Defendants supported, encouraged, and directed employees, front groups, and doctors they identified

[9] West Virginia Department of Health and Human Resources, West Virginia Drug Overdose Deaths Historical Overview 2001-2015, p. 8.
[10] Transcript of use and Abuse of Prescription Painkillers, The Diane Rehm Show (Apr. 21, 2011), http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript.

as "Key Opinion Leaders" (KOLs") to publicize biased and misleading studies and promotional materials and conduct thousands of medical education programs that were deceptive and laced balance. These "educational" efforts were designed not to present a fair view of how and when opioids could be safely and effectively used, but to convince doctors and patients that the benefits of using opioids to treat chronic non-cancer pain outweighed their risks and that opioids could be used safely by most patients.

18. Defendants' representations regarding the benefits, risks, and relative superiority of opioids were – and are – untrue and unsupported by competent scientific evidence. In fact, even Defendants' KOLs initially were very cautious about whether opioids were safe and effective to treat non-cancer pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Still, Defendants continue to disseminate their false and misleading marketing claims.

19. Defendants' marketing not only ignored contrary evidence, but also failed to acknowledge risks disclosed on their own labels and sometimes exceeded the approved indications. For example, Defendant Cephalon marketed its opioid Fentara for chronic non-cancer pain, even though it was approved **only** to treat cancer pain.

20. Both the Manufacturer and Distributor Defendants' strategies are modeled on promotional activities that have been deemed unlawful and for which drug companies and distributors have paid billions of dollars in settlements and judgments. What makes this effort particularly nefarious – and dangerous – is that unlike most other prescription drugs, opioids are highly addictive controlled substances. Defendants deceptively

engaged a patient base that – physically and psychologically – could not turn away from their drugs, many of whom were not helped by the drugs and were profoundly damaged by them.

21. Countless citizens of Jefferson County suffer from chronic non-cancer pain, which takes an enormous toll on their health, their lives, and their families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about treatment risks and benefits.

22. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, inter alia,: (1) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for proving treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; (5) and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered directly, by the Plaintiff.

23. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct. Plaintiff is authorized by law to abate any nuisance and prosecute in any court of competent jurisdiction any person who creates, continues,

contributes to, or suffers such nuisance to exist and prevent injury and annoyance from such nuisance. W. Va. Code § 8-12-5.

24. Plaintiff brings this suit against two classes of Defendants, the Manufacturers and the Wholesale Distributors of prescription opioids.

25. The unlawful marketing, distribution, and sale of prescription opiates by the Defendants named herein has created a serious public health crisis of opioid abuse, addiction, morbidity and mortality and is a public nuisance.

26. The Manufacturers and Distributors intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

27. The Jefferson County Commission brings this action to force the Manufacturer and Distributor Defendants to take responsibility for the opioid epidemic that they have created.

II. PARTIES

A. Plaintiff

28. Plaintiff JEFFERSON COUNTY COMMISSION is a public corporation which may sue and plead in its own name pursuant to W. Va. Code § 7-1-1(a). Plaintiff is a "political subdivision" and is neither an agency nor an agent of the State of West Virginia. W. Va. Code § 29-12A-3(c) [1986]; W. Va. Code § 14-2-3 [1967]; *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969). Plaintiff has all the powers of local self-government and home rule and all other powers possible for a county to have

under the constitution of the State of West Virginia and the laws of the State of West Virginia.

29. Plaintiff has declared, inter alia, that opioid abuse, addiction, morbidity and mortality has created a serious public health and safety crisis, and is a public nuisance, and that the diversion of legally produced controlled substances into the illicit market causes or substantially contributes to this public nuisance.

30. On October 26, 2017, the JEFFERSON COUNTY COMMISSION passed a *Resolution* declaring the unlawful distribution of prescription pain pills a public nuisance, and brings this civil action against the Defendants seeking damages necessary to eliminate the hazard to public health and safety, as well as abate, or cause to be abated, the hazard to public health and safety, as well as abate, or cause to be abated, the public nuisance.[11]

31. Plaintiff has standing to recover damages incurred because of Defendants' actions and omissions. Plaintiff has standing to bring all claims pled herein.

B. Manufacturer Defendants

32. A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers. When marketing a drug, a pharmaceutical manufacturer must tell the truth, which means ensuring that its marketing claims are supported by science and medical experience. The following Manufacturer Defendants broke these simple rules:

[11] Exhibit A, *Resolution on Jefferson County's Opioid Epidemic.*

33. Defendant, PURDUE PHARMACEUTICAL PRODUCTS, LP, is registered with the West Virginia Secretary of State as a Delaware limited partnership with its principal office located in Stamford, Connecticut.

34. Defendant, PURDUE PHARMA, LP, is registered with the West Virginia Secretary of State as a Delaware limited partnership with its principal office located in Stamford, Connecticut.

35. Defendant, THE PURDUE FREDERICK COMPANY, INC., is a Delaware Corporation with its principal office located in Stamford, Connecticut.

36. Defendant, ACTAVIS PHARMA, INC., is registered with the West Virginia Secretary of State as a Delaware corporation with its principal office located in Parsippany, New Jersey.

37. Defendant, ALLERGAN USA, INC., is registered with the West Virginia Secretary of State as a Delaware corporation with its principal office located in Irvine, California.

38. Defendant, ALLERGAN SALES, LLC, is registered with the West Virginia Secretary of State as a Delaware limited liability company with its principal office located in Irvine, California.

39. Defendant, CEPHALON, INC.; is a Delaware Corporation with its principal office located in Frazer, Pennsylvania.

40. Defendant, ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal office located in Titusville, New Jersey.

41. Defendant, JOHNSON & JOHNSON is a New Jersey corporation with its principal office located in Brunswick, New Jersey.

42. Defendant, TEVA PHARMACEUTICALS, INC., is registered with the West Virginia Secretary of State as a Delaware corporation with its principal office located in North Wales, Pennsylvania. In October 2011, Teva acquired distributor, CEPHALON, INC., a Delaware corporation with its principal office located in Frazer Pennsylvania.

43. Defendant, TEVA SALES AND MARKETING, INC., is registered with the West Virginia Secretary of State as a Delaware corporation with its principal office located in Overland Park, Kansas.

44. Defendant, MALLINCKRODT ENTERPRISES, LLC, is registered with the West Virginia Secretary of State as a limited liability company with its principal office in Hazelwood, Missouri.

45. Defendant, MALLINCKRODT ENTERPRISES HOLDINGS, INC., is registered with the West Virginia Secretary of States as a California corporation with its principal office located in Hazelwood, Missouri.

C. Distributor Defendants

46. Likewise, a pharmaceutical distributor should never place its desire for profits above the health and well-being of its customers. A pharmaceutical distributor has the duty to monitor and control the volume of its distribution of a potentially addictive drug to ensure that the drug is not being diverted for harmful use, which means ensuring that its marketing claims are supported by science and medical experience. The following Distributor Defendants broke these simple rules:

47. Defendant, AMERISOURCEBERGEN DRUG CORPORATION, is registered with the West Virginia Secretary of State as a Delaware corporation with its principal office located in Chesterbrook, Pennsylvania.

48. Defendant, CARDINAL HEALTH, INC., is registered with the West Virginia Secretary of State as an Ohio corporation with its principal office located in Dublin, Ohio.

49. Defendant, CARDINAL HEALTH PHARMACY SERVICES, LLC, is registered with the West Virginia Secretary of State as a Delaware limited liability company with its principal office located in Houston, Texas.

50. Defendant, CVS INDIANA, L.L.C., is registered with the West Virginia Secretary of State as an Indiana limited liability company with its principal office located in Woonsocket, Rhode Island.

51. Defendant, ENDO PHARMACEUTICALS, INC., is registered with the West Virginia Secretary of State as a Delaware corporation with its principal office located in Malvern, Pennsylvania.

52. Defendant, ENDO HEALTH SOLUTIONS, INC. is a Delaware Corporation with is principal office located in Malvern, Pennsylvania.

53. Defendant, H.D. SMITH WHOLESALE DRUG CO., is a Delaware corporation with its principal office located in Springfield, Illinois.

54. Defendant, MCKESSON CORPORATION, is registered with the West Virginia Secretary of State as a Delaware Corporation with its principal office located in San Francisco, California.

55. Defendant, RITE AID OF MARYLAND, INC., is registered with the West Virginia Secretary of State as a Maryland corporation with its principal office located in Camp Hill, Pennsylvania.

56. Defendant, WAL-MART STORES EAST, LP, is registered with the West Virginia Secretary of State as a Delaware limited partnership with its primary office located in Little Rock, Arkansas.

57. Defendant, WALGREEN, CO., is registered with the West Virginia Secretary of State an Illinois Corporation with a principal office in Deerfield, Illinois.

III. JURRISDICTION AND VENUE

58. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332 because complete diversity of citizenship exists between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interests and costs.

59. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Plaintiff's claims hinging on 21 USC § 823 and 21 CFR 1301.74 necessarily raise a federal issue which is actually disputed, substantial, and capable of resolution in federal court without disrupting the federal-state balance approved by Congress. *See Gunn v. Minton*, 568 U.S. 251 (2013). This Court further has subject matter jurisdiction under 28 U.S.C. § 1331 because Plaintiff's RICO claims also raise a federal question.

60. This Court has supplemental jurisdiction over Plaintiff's state law claims under 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

61. This Court has personal jurisdiction over the Defendants because they conduct business in West Virginia, purposefully direct or directed their actions toward West Virginia, or consented to be sued in West Virginia by registering with the West Virginia Secretary of State and also have the requisite minimum contacts with West Virginia necessary to constitutionally permit this Court to exercise jurisdiction.

62. Venue is proper in this Court because the Defendants purposefully availed themselves of the market for prescription opioid drugs in Jefferson County, West Virginia, which is located in this District and Division. The Defendants all transact business in this District and Division.

IV. FACTUAL ALLEGATIONS – MANUFACTURER DEFENDANTS

A. Because of their known serious side effects and the risk of addiction, opioids were rarely prescribed by physicians before the Defendants' pervasive and deceptive marketing campaign.

63. Opioids have long been approved and accepted for the treatment of chronic cancer pain. Opioids are appropriate for this use given the severity of pain often associated with cancer and the recognition that the benefits of treating that pain outweigh the potential risk of addiction, especially for terminal patients. The same is not true for chronic non-cancer pain. Among other differences, the pathology responsible for cancer pain is distinct from the pathologies that cause chronic pain. For patients with cancer, the source of their pain is likely to be the tumor and pressure on, or erosion of nerves or bones. Chronic pain arises from multiple sources, including musculoskeletal (from joints, ligaments, or muscles), neuropathic (nerve-related occurring in diseases like diabetes or

shingles), headache, or functional pain (arising from disease states such as irritable bowel) that respond differently – or not at all – to opioids.

64. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic non-cancer pain. As admitted in 1994 by Dr. Russel Portenoy, a KOL who tirelessly promoted opioid therapy for the treatment of chronic non-cancer pain, the medical consensus before the Manufacturer Defendants' "reeducation" campaign was decidedly against the use of opioids to treat chronic non-cancer pain:

> **The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs.** This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse side effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. **Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects.** There is an implicit assumption that little separates these outcomes from the outcomes from the highly aberrant behaviors associated with addiction.[12]

65. Dr. Portenoy left no doubt about the 1994 state of knowledge concerning the safety and efficacy of opioid therapy for long-term chronic non-cancer pain: "At the present time, neither the medical literature nor clinical experience provides compelling

[12] Portenoy, *supra* note 2, at 247 (emphasis added).

evidence that long-term opioid use would be salutary for more than a very small number of patients with chronic nonmalignant pain."[13]

66. The lack of any credible science supporting opioid therapy for chronic non-cancer pain did not deter the Defendants from marketing opioid therapy for that use. Working with and through KOLs like Dr. Portenoy, Defendants seized on anecdotal accounts of opioid efficacy in limited populations and methodically, through numerous publications, programs, and spokespeople, overstated the benefits and understated the risks of opioids to create and defend a broad market for opioids, a market that never should have and never would have come to exist absent Defendants' concerted, deliberate, and patently misleading efforts. Through marketing as pervasive as it was deceptive, the Manufacturer Defendants convinced health care providers and consumers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven.

67. By the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate – and often first-line – treatment for chronic pain conditions. The Manufacturer Defendants not only marketed opioids for chronic pain conditions, but targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate both Defendants' marketing and patients' pain conditions.

[13] *Id.* at 278.

68. Thus, the Manufacturer Defendants deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and required opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

B. Defendants' marketing of opioids to treat long-term, non-cancer pain was false, misleading, imbalanced, and unsupported by science.

69. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing or prescription drugs. Drug makers' claims in promotional materials must be supported by "substantial" scientific evidence and cannot be false or misleading. 21 U.S.C. § 352(a). The materials must reflect a "fair balance," accurately and comprehensively describing the risks and benefits of the drug, and cannot ignore or minimize a drug's risk or overstate its benefits. 21 C.F.R. § 202.1(e)(3), 1.21(a). It is a violation of federal law for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. § 99.101(a)(4).

70. Drug companies are also prohibited from making comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience." 21 C.F.R. § 201.1(6)(ii). While the FDA must approve a drug's label – defined to include all explanatory material accompanying the label, 21 U.S.C. §§ 321(k), (m) – it is the drug

company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information. *See* 21 CFR § 201.56 (providing general requirements for prescription drug labeling); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 CFR § 314.70(c)(2) (allowing manufacturers to make changes that "strengthen . . . a warning, precaution, or adverse reaction"). In addition, while promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated, the FDA does not have to approve these materials in advance. If, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations that it deems less serious, while warning letters are reserved for violations that affect patients' safety or reflect continued violations of the law.

71. For years, Defendants systematically violated these federal laws, as well as multiple state laws, requiring that the promotion of pharmaceutical drugs not be false, deceptive, or misleading. Defendants manipulated and ignored scientific evidence to formulate and broadcast the misrepresentations described below, each of which was instrumental in: (1) overcoming longstanding medical and legal barriers to opioid therapy for chronic non-cancer pain; and (2) making high-dose, long-term opioid use the new "gold standard" of treatment for chronic non-cancer pain.

72. Defendants also circumvented these rules whenever possible, disseminating much of their false, misleading, imbalanced, and unsupported statements through unbranded marketing materials – materials that generally promoted opioid use but did not

reference any particular opioid drug by name. Upon information and belief, Defendants used these unbranded materials, which are not reviewed by the FDA, to disseminate messages that were inaccurate, were inconsistent with their branded marketing materials and the drugs' labels and package inserts, and would not pass muster with the FDA. Had they relied on branded materials, the FDA-required drug labels and package inserts would have been included to more fully describe the risks and administration of opioids.

73. Defendants relied heavily on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. Defendants developed national, company-wide marketing strategies, which, upon information and belief based on this large-scale strategy and uniformity of messaging, were applied throughout West Virginia, including in Jefferson County and the surrounding areas.

74. Doctors and other prescribers are the gatekeepers for all prescription drugs so, unsurprisingly, Defendants focused the bulk of their marketing efforts, and their multi-million dollar budgets, on the professional medical community. Particularly because of barriers to prescribing regulated drugs like opioids, Defendants knew doctors would not treat patients with common chronic non-cancer pain complaints with opioids unless doctors were persuaded that opioids had substantial real benefits and minimal risks. Through misleading medical education programs, treatment guidelines, and other efforts, Defendants "reeducated" general practitioners and family doctors. They knew that these doctors reach the vast majority of patients with common chronic pain complaints, but are less likely than specialists to have the time or knowledge to evaluate Defendants'

deceptive messages or to closely monitor patients for signs of improvement or adverse outcomes.

75. Defendants also marketed directly to patients to: (1) encourage them to ask doctors for opioids to relieve chronic non-cancer pain; and (2) allay their well-founded concerns that opioids were dangerous and addictive. Defendants targeted particularly vulnerable, but usually well-insured, groups of patients, such as veterans and the elderly. Defendants leveraged and funded patient organizations and communities – promoting opioids particularly for common conditions, such as headaches, arthritis, fibromyalgia, and back pain. Unlike other direct-to-consumer marketing, Defendants as a group, focused on unbranded advertising knowing that the creation of a new, expansive market for opioids would benefit all manufacturers.

B(1). Defendants misrepresented and overstated the benefits of long-term opioid therapy for chronic non-cancer pain while failing to disclose the lack of evidence supporting the benefits and efficacy of long-term use.

76. Defendants deceptively promoted opioids as improving chronic non-cancer patients' function by allowing them to get back to "normal" and reducing their pain long-term. Defendants misrepresented the efficacy of opioids in an effort to persuade doctors and patients that their benefits outweighed the risks.

77. Although opioids may initially improve patients' function in the short term there were – and are – no controlled studies of the use of opioids beyond 16 weeks and no evidence that opioids improve patients' function long-term.[14] Despite this lack of

[14] Jeffrey Dersh et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) Spine, 2219-2227 (Sept. 15, 2008).

evidence – and the existence of evidence to the contrary – Defendants consistently promoted opioids as capable of improving patients' function and quality of life.

78. Importantly, after a "systematic review of the best available evidence" by a panel that excluded experts with conflicts of interest, the CDC published its 2016 *Guideline for Prescribing Opioids for Chronic Pain* ("CDC Guideline"). The CDC Guideline makes clear that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[15] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)"[16] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids used longer than 12 weeks."[17] As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

79. The FDA has recognized that claims that opioids improve patients' function are misleading. For example, a company claimed that its opioid "Improved overall Function," offered "Long Lasting Improvements in Physical Function," and would enable patients to be better able to engage in a list of daily activities, such as walking, standing,

[15] CDC Guideline at 10.
[16] *Id.* at 9.
[17] Letter from Janet Woodcock, M.D., Dir., Center for Drug Eval. And Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

and climbing stairs. In a warning letter sent March 24, 2008, the FDA publicly made clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

80. Nevertheless, upon information and belief, Defendants touted the purported benefits of long-term opioid use while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

81. In marketing Kadian, Actavis made implied claims that the drug would allow chronic non-cancer patients to return to work, relieve "stress on your body and your mental health," and help them enjoy their live. The FDA found that Defendant Actavis misrepresented the scientific evidence: "[W]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[18]

82. Defendant Janssen distributed a series of posters to doctors' offices that showed pictures of people dressed for a variety of active professions suggesting that doctors prescribe Ultracet because "Pain doesn't fit into their schedule." Despite the lack of scientific evidence in support of such a claim, the posters falsely implied that Ultracet

[18] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Voothe, CEO Actavis Elizabeth LLC (Feb. 18, 2010).

was appropriate for help in maintaining an active lifestyle. Several of the posters contained the tagline "Ultracet lets them perform."

83. In spite of the complete lack of scientific basis, in 2011, Purdue sponsored *A Policymaker's Guide to Understanding Pain & Its Management*, published by the American Pain Foundation ("APF"), which asserted that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic non-cancer pain patients. To support this claim, APF cited *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, a study published in 2006 in the Canadian Medical Association Journal. However, the study concludes: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The Purdue-Sponsored *Guide* failed to disclose this conclusion, as well as the fact that the study was conducted only for five weeks, and therefore could not support the long-term use of opioids, or the study's findings that opioids were actually less effective than alternative treatments.

84. Further, two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Defendant Purdue. Upon information and belief, Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement,

Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. Dr. Portenoy, a pain management specialist who received Purdue research grants and was a Purdue consultant, was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

85. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which recommended the use of opioids to treat chronic pain. Treatment guidelines like the AAPM/APS Guidelines were particularly important to Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received financial support from Defendant Purdue, eight from Defendant Teva, nine from Defendant Janssen, and ten from Defendant Endo.

86. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, **even with a prior history of drug abuse**. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies including Purdue, Endo, Janssen, and Teva made to the sponsoring organizations and committee members.

87. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who also served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

88. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, have been a particularly effective channel of deception, and have influenced not only treating physicians, but also the body of scientific evidence on opioids.

89. Defendants' misrepresentations about increased function are particularly misleading for specific indications for which they promoted opioids, such as migraines and lower back pain. For instance, research indicates that as many as 30% of patients who suffer from migraines have used opioids to treat their headaches.[19] Despite this, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment ("MIDAS"), and had higher rates of depression compared to non-opioid users.[20]. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.[21] Studies of the use of opioids long-term for

[19] Dawn C. Buse, *Opioid Use and Dependence Among Persons With Migraine: Results of the AMPP Study*, 52 Headache: The Journal of Head & Face Pain, 18-236 (Jan. 2012).
[20] *Id.*
[21] *Press Kits – Migraine Patients Taking Addictive Or Non Approved FDA Migraine Treatment*, National Headache Foundation (May 15, 2007),

chronic lower back pain similarly have been unable to demonstrate an improvement in patients' function.[22]

90. As a pain specialist noted in an article titled *Are We Making Pain Patients Worse?,* "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally." Instead, at higher doses, patients are much more likely to develop dependence or addiction, experience pain deterioration due to hyperalgesia, and are three to nine times more likely to die from opioid-related causes than those on low doses.[23]. Additionally, epidemiological data suggest that only a minority of patients on chronic opioid therapy benefit from the drugs and most continue to suffer significant pain and limitations on their activities. Defendants have never disclosed these facts.

B(2). Defendants misrepresented the adverse outcomes and risks of opioid use for chronic non-cancer pain.

91. To convince prescribers and patients that opioids are safe, Defendants deceptively represented that the risk of abuse and addiction is modest, manageable, and limited to illegitimate patients, not those with genuine pain. To reach chronic non-cancer

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http://www.headaches.org/press/NHF_Press_Kits_Migraine_Patients_Taking_Addictive_OR_Non_Approved_FDA_Migraine_Treatments.

[22] Luis E. Chaparro, *Opioids compared to placebo or other treatments for chronic low-back pain,* 8 Cochrane Database of Sytematic Reviews (2013).

[23] Tara Gomes et al., *Opioid dose and drug-related mortality in patients with nonmalignant pain,* 171(17) Archives of Internal Med., 686-691 (apr. 11, 2011); Kate M. Dunn et al., *Opioid prescriptions for chronic pain and overdose: a cohort study,* 152(2) Annals of Internal Med., 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal. *Id. See also* J.B. Braden et al., *Emergency Department visits among recipients of chronic opioid therapy,* 170(16) Archives of Internal Med., 1425-1432 (Sept. 13, 2010) (finding that higher doses of opioids doubled the risk of adverse drug events).

cancer pain patients, Defendants had to overcome doctors' legitimate fears that opioids would addict their patients. The risk of addiction is an extremely weighty risk – condemning patients to, among other things, dependence, compulsive use, haziness and dullness of mind, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death.

92. Remarkably, the Defendants successfully effected a sea change in the perception of opioid pain medication even though opioids are controlled substances classified under the federal CSA as having "high potential for abuse" and a "risk of severe psychological and physical dependence."[24] Defendants: (1) brazenly maintained that the risk of addiction for patients who take opioids long-term was low; and (2) omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk – and Defendants' own FDA labels – compelled disclosure.

93. To convince prescribers and patients that opioids are safe, Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, (3) all other patients could sagely be prescribed opioids, and (4) even high-risk patients could be prescribed opioids if closely managed.

[24] 21 U.S.C. § 812(b).

94. Contrary to Defendants' claims, numerous studies support that, though these patients may not presently show signs of abuse or addiction, at least 15% and as many as 40% of patients will become addicted to opioids.[25] Research has shown that opioids are even more addictive than cocaine and alcohol. One in three to five users who self-administer short-acting opioids will become addicted, versus one in eight to fifteen for users of cocaine or alcohol.[26]

95. Defendants' sales representatives regularly omitted from their sales conversations with prescribers any discussion of the risk of addiction from long-term use of opioids. These omissions rendered other arguably truthful statements about opioids false and misleading, and they both reinforced and failed to correct their prior misrepresentations regarding the risk of addiction.

96. Defendants consistently minimized the risk of addiction inherent in the long-term use of opioids for non-cancer pain. To ensure that sales representatives delivered the desired messages to prescribers, Purdue, Endo, Cephalon, and Janssen directed and monitored their respective sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit. These Defendants likewise required their sales representatives to use

[25] (*E.g.*, Joseph A. Boscarino et al., *Risk Factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction, 1776-1782 (Oct. 2010); Joseph A. Boscarino et al., *Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 vs. DSM-4 diagnostic criteria*, 30(3) Journal of Addictive Diseases, 185-194 (July-Sept. 2011); *Prescription Drugs: Abuse and Addiction*, National Inst. On Drug Abuse, (Oct. 2011), http://www.drugabuse.gov/sites/default/files/rrprescription.pdf.)

[26] Mary J. Kreek et al., *Pharmacotherapy of Addictions*, 1(9) Nature Reviews: Drug Discovery, 710-726 (Sept. 2002).

sales aids reviewed, approved, and supplied by the companies and forbade them to use promotional materials not approved by the company's marketing and compliance departments. They further ensured marketing consistency nationwide through national and regional sales representative training. Thus, Defendants' sales forces in West Virginia used the same deceptive messages about the risks and benefits of its opioids that the companies employed nationwide.

97. Defendants' marketing materials failed to portray the risk of abuse or addiction. For example, in a Janssen-sponsored publication, *Finding Relief: Pain Management for Older Adults,* published in 2009 and still available online, Janssen asserts as "Fact" that "opioids are *rarely* addictive when used properly for the management of chronic pain." (Emphasis in the original).[27] Similarly, Endo promised on a website it funded that "People who take opioids as prescribed usually do not become addicted."

98. Defendants also deceptively undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to specific, high-risk patients. According to Defendants, doctors can screen patients to identify those who are likely to become addicted, and therefore could safely prescribe to everyone else. Defendants discounted general concerns or warnings regarding addiction by reassuring doctors that their patients would not become addicted so long as they are prescribed to legitimate patients with actual pain.

[27] http://www.managepaintoday.com/news/-Finding-Relief-Pain-Management-for-Older-Adults

99. These assurances were false and unsafe, as prescribers cannot accurately predict which patients are at higher risk of addiction. A 2004 Endo patient education publication, edited by KOL Dr. Russell Portenoy, and titled, *Understanding Your Pain: Taking Oral Opioid Analgesics*,[28] which is still available online, answers the hypothetical patient question – "What should I know about opioids and addiction?" – by focusing on explaining what addiction is ("a chronic brain disease") and is not ("taking opioids for pain relief)." It goes on to explain that, "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction."

100. More graphically, a Purdue brochure, upon information and belief still provided to doctors today, falsely portrays "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse*[29], a pamphlet published in 2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids – skin popping, track marks, and perforated nasal septa – under the heading "Indications of Possible Drug Abuse." Purdue knew that opioid addicts who resort to these extremes are uncommon; people more typically become dependent through oral use of opioids. According to briefing materials Purdue submitted to the FDA in October 2011, OxyContin was used non-medically by injection as little as 4% of the time.

[28] http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf
[29] *Providing Relief, Preventing Abuse: A reference guide to controlled substance prescribing practices*, Purdue Pharma L.P. (Stamford, CT), 2d ed. 2011, 13).

101. Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk[] of . . . addiction" – "even at recommended doses" – of all opioids.[30]

102. Defendants falsely instructed prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies mitigate addiction risk.

103. There are three fundamental flaws in Defendants' assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that screening works to substantially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients can be given opioids sagely, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients without red flags can take opioids long-term without significant danger of addiction.

104. KOL Dr. Russell Portenoy appeared on *Good Morning America,* in 2010, to discuss the use of opioids long-term to treat chronic non-cancer pain. He claimed that, "[a]ddiction, when treating pain, is distinctly uncommon. If a person does not have a

[30] *FDA announces safety labeling changes and postmarket study requirements for extended release and long-acting opioid analgesics,* FDA (Sep. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016.

history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."

105. A Cephalon-sponsored guide, *Opioid Medications and REMS: A Patient's Guide*, similarly claimed: "Some people are nervous about taking opioids because they are afraid they will become addicted. However, patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

106. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids,* emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could sagely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

107. In 2012, the same KOL also present at a Purdue sponsored CME, *Chronic Pain Managing and Opioid Use: Easing Fars, Managing Risks, and Improving Outcomes,* in which he discussed the treatment of a high-risk chronic pain patient demonstrating signs of opioid addiction. The presentation recommended that doctors facing a similar patient use the same old screening tools. He also stated that doctors should consider reducing the frequency of prescription fills and switching to a different opioid. Regardless of the course taken, the message was clear: continue opioid therapy.

108. Many of Defendants' misrepresentations about opioid abuse and addiction risk were particularly dangerous because they were aimed at general practitioners or family

doctors who treat many chronic conditions, but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. Defendants have made a concerted effort to reach these practitioners through continuing medical education programs, office visits, and literature specifically aimed at them, and most opioids are prescribed by primary care physicians.[31]

109. The CDC Guideline confirms the falsity of Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools or patient contracts – "for improving outcomes related to overdose, addiction, abuse, or misuse." The Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule our risks from long-term opioid therapy."[32]

B(3). Defendants attempted to obscure the true incidence of opioid addiction by creating tenuous distinction between physical dependence and full-blown addiction.

110. In an effort to underplay the risk and impact of addiction, Defendants frequently claim that while patients may become "physically dependent" on opioids, physical dependence is not the same as addiction and can be addressed by gradually tapering patients' dosage to avoid the adverse effects of withdrawal.

[31] Wolters Kluwer Health, *Sharp rise in opioid drugs prescribed for noncancer pain,* Science Daiy (Sept. 16, 2013), http://www.sciencedaily.com/releases/2012/09/130916091218.htm.
[32] CDC Guideline, 28.

111. For example, in the April 2, 2010, version of its OxyContin label, Purdue states: "**Cessation of Therapy** When the patient no longer requires therapy with OxyContin, taper the dose gradually to prevent signs and symptoms of withdrawal in the physically-dependent patient." The APF *Policymaker's Guide* (2011) funded by Purdue states: "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation."[33]

112. Defendants' so-called guidance overstates the ease of withdrawing from long-term use of opioids and the adverse effects that accompany their discontinuance. Withdrawal from opioids after long-term use can trigger severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms. The dependence on opioids can be so severe that withdrawal symptoms may persist for months, or even years, after a complete withdrawal from the drugs.

113. Defendants also fail to disclose that long-term opioid use often causes psychological, as well as physical, dependence. Addiction is not a switch that is either off or on. Indeed, as the most recent, authoritative Diagnostic and Statistical manual of Mental Disorders ("DSM-V") acknowledges, there is a spectrum of disorders that range from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on that spectrum.[34]

[33] *A Policymaker's Guide to Understanding Pain & Its Mgmnt.*, A. Pain Found., Oct 2011 at 31.
[34] For that reason, references to "addiction" in this Complaint refer to this spectrum of substance abuse disorders.

114. This is certainly true of opioids. Anxiety over ending opioid use can trigger cravings for opioids, even after a patient is no longer physically dependent and despite the fact that he or she is not deriving benefits from the treatment. As Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, explains, opioids "hijack[] the brain's reward system," convincing users that "the drug is needed to stay alive."[35] Even absent physical dependence, a patient's fear of the unpleasant effects of discontinuing opioids can cause patients to seek the drugs.[36]

115. Thus, ending opioid therapy is not, as Defendants claim, "simply" a matter of gradually lowering a patient's dosage over time. In fact, one of the significant risks in beginning chronic opioid therapy is that, once patients become physically dependent, it will be difficult for them to ever stop using opioids. According to one study, more than half of patients who continuously use opioids for more than 90 days remain on opioids after more than five years.[37] Most patients who become physically dependent after long-term use will require opioid maintenance (through methadone or buprenorphine) for years or decades. Defendants fail to disclose this significant risk to doctors and patients.

116. A publication in Purdue's catalog of publications for providers, *Providing Relief, Preventing Abuse*, cautions against the "common error" of confusing physical dependence with addiction. It analogizes physical dependence on opioids to physical

[35] David Montero, *Actor's Death Sows Doubt Among O.C.'s Recovering Opioid Addicts,* The Orange Cnty. Register (Feb. 3, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html.
[36] Jane C. Ballantyne & Cathy Stannard, *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain with Opioids*, 21(5) Pain: Clinical Updates, 1-7 (Dec. 2013).
[37] Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12) Journal of Gen. Internal Med., 1450-1457 (Dec. 2011).

dependence on antihypertensives (blood pressure medicine) or decongestants, but this analogy has no basis in fact. With non-addictive drugs, like blood pressure medicine, patients may experience withdrawal symptoms, but they are rarely difficult to get over, and there is no craving for the drug. However, with long-term use of opioids, even in the absence of a formal diagnosis of addiction, patients often crave the drug long after they have discontinued use. Patients on opioids long-term will often experience symptoms that arguably may not qualify as full-blown addiction, but are not mere physical dependence. Defendants' marketing failed to acknowledge the spectrum of substance abuse disorders short of full-blown addiction, which also are cause for concern, and created the sense that doctors need only concern themselves with signs of full-blown addiction.

117. As with the claimed low incidence of addiction, the misrepresentation that chronic opioid therapy is easy to stop is important to Defendants' fraudulent marketing scheme. Honestly describing the difficulty of discontinuing opioid medication after long-term use and the complexity of patients' dependence would rebalance the risk-benefit analysis and stoke doctors' and patients' well-grounded concerns that once on opioids, severe physical and psychological dependence would make it extremely difficult for patients to ever stop their use. It might also motivate the general practitioners to whom Defendants generally marketed opioids for long-term use to refer patients requesting opioids to pain management specialists who would not so easily prescribe them. Defendants also gave GPs a false sense of confidence that they could identify addiction, distinct from physical dependence, which, again, allowed them to believe that they could

continue to responsibly prescribe opioids. Defendants chose not to tell the truth so that they could sell more drugs.

B(4). Defendants falsely described addiction as the unfounded condition, pseudoaddction, and dangerously encouraged doctors to respond by prescribing even more opioids.

118. Defendants needed a way to explain why so many chronic non-cancer pain patients on opioids seem to be addicted: they ask for drugs by name, they seek refills earlier than their supplies should have run out, hoard drugs, or self escalate their dosages.

119. Defendants deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition they called "pseudoaddicition." Pseudoaddiction was a concept invented to convey the idea that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids – the medical equivalent of fighting fire by adding more fuel.

120. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

121. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding

NIPC projects; developing, specifying, and reviewing content and distributing NIPC materials.

122. Dr. Portenoy, again, an ostensibly independent "key opinion leader" for Endo, Janssen, Cephalon, and Purdue, popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

123. Dr. Portenoy took the deception of pseudoaddiction one step farther, separating from a list of commonly accepted signs of drug addiction those he claimed were "probably less predictive of addiction."[38] Portenoy's "less predictive" list included:

a) Aggressive complaining about the need for more drugs;

b) Drug hoarding during periods of reduced symptoms;

c) Requesting specific drugs;

d) Openly acquiring similar drugs from other medical sources;

e) Unsanctioned dose escalation or other noncompliance with therapy on one or two occasions;

f) Unapproved use of the drug to treat other symptoms;

g) Reporting psychic effects not intended by the clinician; and

h) Resistance to a change in therapy associated with "tolerable" adverse effects with expressions of anxiety related to the return of severe symptoms.

[38] Portenoy, *supra*, note 1, at 267, Table 3.

124. Portenoy cited no authority for his "less predictive of addiction" conclusion and is not himself a specialist or authority in addiction medicine. Yet his list encouraged doctors to ignore these obvious signs of addiction and **prescribe more opioids**.

125. The CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that the prescribers increase opioid doses if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment are unlikely to experience pain relief with longer-term use,"[39] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[40]

B(5). Rather that honestly disclose the risk of addiction, Defendants deflected attention from the prevalence and likelihood of addiction to the alleged pervasiveness of undertreated pain.

126. As public concern about prescription opioid addiction began to emerge, Defendants attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. They claimed that purportedly overblown worries about addiction caused pain to be under-treated and opioids to be over-regulated and under-prescribed. One APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, stated that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty

[39] CDC Guideline, at 13.
[40] Id. at 25.

in obtaining adequate care include . . . misconceptions about opioid addiction." The Purdue Guide further alleged that resulting regulatory constraints (like the FDA's recently mandated prescriber education program, or REMS ("Risk Evaluation and Mitigation Strategies")) have a "chilling effect" on prescribing and that abuse of opioids injured and "jeopardize[d] effective pain management by impeding patient access to opioids."

127. A Purdue website called *In the Face of Pain* complained, under the heading of "Protecting Access," that through at least mid-2013, policy governing the prescribing of opioids was "at odds with" best medical practices by "unduly restricting the amounts that can be prescribed and dispensed;" "restricting access to patients with pain who also have a history of substance abuse;" and "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe."[41] This unsupported and untrue rhetoric aimed to portray doctors who did not prescribe opioids as uncaring, converting their desire to relieve patients' suffering into a mandate to prescribe opioids.

B(6). Defendants downplayed, mischaracterized, or simply omitted to fully disclose the full panoply of adverse effects associated with long-term use of opioids.

128. In addition to failing to disclose the true risk of addiction that accompanies long-term use of opioid medication, the Defendants have also misrepresented the risks of other associated use by describing them as minor and short-term and failing to disclose

[41] *See In the Face of Pain Fact Sheet: Providing Access to Pain Treatment*, Purdue Pharma L.P. (2013), www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf.

the most significant risks. Defendants most frequently highlight the risk of constipation, which they advise can be addressed with laxatives or other treatments. The other side effects Defendants typically disclose are drowsiness, nausea and vomiting, mental clouding, and itching. Defendants promise that these symptoms will go away within days of starting use.

129. Defendants do not disclose far more significant adverse outcomes linked to long-term opioid use, including: hyperalgesia, immunologic and hormonal dysfunction, respiratory depression, apnea, tolerance/loss of analgesic efficacy, endocrinopathies (most notably testosterone depletion, which, among other impacts, may decrease pain tolerance and the effectiveness of opioids),[42] cognitive impairment, dependence, and addiction. These adverse outcomes can result in an increase in falls and fractures in the elderly (which can shorten the lives of elderly patients), overuse, overdose, and death. Defendants also fail to disclose the risk that infants born to pregnant women using opioids will be dependent on opioids as well, suffering a condition called neonatal abstinence syndrome when they painfully withdraw from the drug after birth.[43] In addition, though the labels for opioids contain numerous warnings about use of opioids for patients who have certain conditions, are opioid naive (new to opioids) or use other drugs, Defendants' marketing materials contain no similar cautions.

[42] H.W. Daniell, *Hypogonadism in men consuming sustained-action oral opioids*, 3(5) The Journal of Pain, 377-384 (Oct. 2002); Nathaniel Katz and Norman A. Mazer, *Impact of opioids on the endocrine system*, 25 The Clinical Journal of Pain, 170-175 (2009).

[43] The FDA now requires a boxed warning on all extended release and long acting opioids, cautioning that chronic use of those drugs by pregnant women can result in neonatal opioid withdrawal syndrome ("NOWS"), which may be life threatening and require specialized care.

130. Defendants suppressed and mischaracterized the truth about the consequences of long-term opioid use.

131. Janssen's marketing campaign for Nucynta was particularly deceptive in that it promoted Nucynta's "tolerability," which is completely at odds with and misrepresents its serious side effects. In October 2009, Janssen began to run an advertisement in *Medical Economics* that proclaimed: "OPIOID EFFICACY MEETS UNEXPECTED TOLERABILITY," even though the risk of addiction and serious side effects make opioids intolerable for most patients. While the "tolerability" to which Janssen referred was a lack of GI related side effect (*e.g.*, nausea and vomiting), a reader could only learn this after examining a bar chart representing the study's results. Thus, the all-caps claim of "unexpected tolerability" falsely implied that Nucynta could be taken without severe side effects or consequences.

132. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDS (the actual figure is approximately 3,200, far fewer than from opioids).[44] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

[44] The higher figure reflects deaths from all causes.

133. Purdue sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, in which it taught that NSAIDs and other drugs, but not opioids, are usage at high doses.

134. Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See, e.g., Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause nothing more than temporary "upset stomach or sleepiness" and constipation.]

135. For example, a Cochrane Collaboration review of evidence relating to the use of opioids for chronic non-cancer pain found that 22% of patients in opioid trials dropped out because of the "intolerable effects" of opioids.[45] Defendants were aware of this high drop-out rate as they pushed the FDA to allow them to exclude these patients from clinical trial data, a method of research known as "enriched enrollment," which allowed drug companies to study only those patients whose negative reactions to opioids did not cause them to stop taking them.

[45] Meredith Noble M *et al*., *Long-term opioid managementTerm Opioid Management for chronic noncancer painChronic Noncancer Pain* (*Review*), Cochrane Database of Sytemic Reviews, Issue 1, 11 (2010).

136. Defendants' misleading treatment of the serious risks of opioid treatment in unbranded materials directly contradicts the disclosures they made on their own labels. The label for Purdue's OxyContin, for example, acknowledges that its use may increase the risk of serious adverse reactions, "including respiratory depression, apnea, respiratory arrest, circulatory depression, hypotension, or shock[.]" Likewise, the label for Janssen's Duragesic includes the warning that "[r]espiratory depression is the chief hazard of" Duragesic, and it "has a narrow indication and should be prescribed only by healthcare professionals who are knowledgeable in the administration of potent opioids and management of chronic pain.". The labels even include warnings for interactions with substances as commonly used as alcohol, as in the Nucynta ER label, which says that the drug "may be expected to have additive effects when used in conjunction with alcohol . . . [and] respiratory depression, hypotension, and profound sedation, coma or death may result." Yet, upon information and belief, these risks are not highlighted in the educational programs and marketing material Defendants have sponsored and disseminated; materials that are much more widely read and relied upon than the drug labels.

137. Defendants' pattern of understating the risks of chronic opioid therapies marred the CMEs and studies they funded or sponsored and left providers with the impression that opioids were much safer than they are and should be used more frequently. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded article on opioids versus another group who reviewed a non-industry funded article. The study did

not mention opioid-related death once. The non-industry funded article mentioned opioid-related death 26 times. A summary of the study notes that students who read the industry-funded article more frequently cited the impression that opioids were underused in chronic non-cancer pain. Those reading the non-industry-funded article, in reporting their "take-aways," mentioned the risk of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty providers have in screening and accounting for source bias.[46]

138. Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDS reports that the quantity of opioids dispensed per capita trebled from 1999 to 2015.

C. Communicating both directly and through agents, the Manufacturer Defendants caused their misrepresentations to be broadly disseminated, thereby increasing opioid prescriptions and use.

139. Defendants have polluted virtually every resource for information on the use of opioids to treat chronic non-cancer pain and have created a deceptively solid foundation of core material, cited and relied upon by others, to minimize the risks and overstate the benefits of using opioids to treat chronic non-cancer pain – both directly and indirectly – through doctors, medical education courses, seemingly independent patient

[46] Mark Olfson et al., *Nat'l Trends in the office-based prescription of schedule II opioids*, 74(9) The Journal of Clinical Psychiatry, 932-939 (Sept 2014).

advocacy groups, and professional societies. Defendants have ensured that their messages reach and expand the market for opioids.

140. Further, Defendants have identified, encouraged, and compensated high profile KOLs to give talks and advice and author books and articles. Defendants' KOLs offer and serve on the program committees that choose CMEs, and develop and promote treatment guidelines that promote chronic opioid therapy. Many of these groups and KOLs may have been misled by Defendants in the same manner as general practitioners and family doctors.

141. Directly and through public relations firms they hire, and advocacy groups and professional societies they finance and influence, Defendants have funded, drafted, edited, approved, published, and distributed websites, books, patient education brochures, videos, and other materials that carry their misrepresentations to targeted groups of doctors (such as family doctors), and patients – particularly veterans and the elderly. Defendants carry out their fraudulent promotions, both individually and in concert with other industry front groups and each other and make and disseminate these misrepresentations throughout the County.

C(1). Method 1: Key Opinion Leaders

142. Defendants routinely rely on a small circle of doctors to promote the use of opioids for the treatment of chronic non-cancer pain. These doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research in order to support the broad use of opioid therapy for chronic non-cancer pain. Known by industry shorthand as "KOLs," or key opinion leaders, they have

written, consulted on, edited, and lent their names to books and articles and given speeches and CMEs supportive of chronic opioid therapy. They served on committees that developed treatment guidelines that, even while acknowledging the lack of evidence for their positions, strongly encourage the use of opioids to treat chronic non-cancer pain.

143. Defendants' KOLs have served on the boards of the advocacy groups and professional societies that develop and offer CMEs and publish patient education materials on opioids.

144. What Defendants and the KOLs rarely disclose is the substantial sums of money Defendants have paid to the KOLs for consulting and speaking arrangements and to serve on various panels and boards; as well as through purported "research grants." Some KOLs have even gone on to become direct employees and executives of Defendants. Dr. Haddox, for example, was a KOL who, as a physician in private practice, promoted widespread opioid use for chronic non-cancer pain. He was a paid speaker and consultant for Purdue, then became a Purdue senior manager.

145. While some KOLs may initially have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Defendants selected and funded doctors whose public positions were unequivocal and supportive of using opioids to treat chronic non-cancer pain.[47] These doctors' professional reputations

[47] Opioid makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used key opinion leaders in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's

were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

146. The KOLs' association with Defendants provided not only money, but also prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community. Upon information and belief, using these KOLs is a central part of Defendants' marketing plans and critical to persuading regulators and doctors – who rely heavily and more uncritically on their peers – that the benefits of chronic opioid therapy outweigh its risks.

147. Dr. Portenoy, who was Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who Defendants identified and co-opted to further their marketing campaign. With Defendants' support, Dr. Portenoy was dubbed the "King of Pain" by Time Magazine. He co-authored *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases* (1986), which asserted, based solely on 38 cases, that chronic opioid therapy was a safe and effective treatment for patients with intractable non-malignant pain.

148. Dr. Portenoy, and other KOLs, thus helped to open the door for the use of opioids to treat chronic non-cancer pain. He served on the American Pain Society/American Academy of Pain Medicine Guidelines Committee, which endorsed the use of opioids to treat chronic non-cancer pain, and the FDA Anesthetic and Lifer Support Drugs Advisory Committee, one of a host of FDA advisory committees that

views. He was dropped when he criticized low tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

serve to provide expertise and technical assistance to assist the FDA decision-making. While he held these position, he also was receiving research support, consulting fees, or honoraria from Defendants Cephalon, Endo, Janssen, and Purdue (among others), and was paid consultant to Cephalon and Purdue.

149. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research. He is a Senior Editor of the *Pain Medicine Journal*, which published numerous articles supportive of chronic opioid therapy. He was President, and is a current board member, of AAPM, a front group that ardently supported chronic opioid therapy. Dr. Webster is the author of numerous CME programs, sponsored by Defendants, which contained virtually all of Defendants' misrepresentations described above. At the same time, Dr. Webster was receiving significant funding (including nearly $2 million from Cephalon).

150. In a blow to Defendants' marketing campaign, Drs. Portenoy and Webster recently acknowledged shortcomings in their pro-opioid positions. Dr. Webster has admitted that the concept of pseudoaddiction – taking patients at their word and assuming they are not addicts, but just need more pain relief "-became too much of an excuse to give patients more medication . . . It is already something we are debunking as a concept."[48] Dr. Portenoy has admitted that he gave "innumerable lectures in the late 1980s and '90s" in which he asserted that fewer than 1% of patients would become addicted to opioids that weren't true. Because the primary goal was to "destigmatize"

[48] Ed Silverman, *Opioids & An Overdue Debate Probe: Kolodny Explains*, Pharmalot.com (May 14, 2012), http://www.pharmalot.com/2012/05/opioids-an-overdue-senate-probe-kolodny-explains/.

opioids, he said, "we often left evidence behind." Dr. Portenoy also conceded that "data about the effectiveness of opioids does not exist."[49]

C(2). Method 2: Co-opting of chronic pain advocacy and research groups

151. A key component of Defendants' plans to promote the long-term use of opioids was coopting pain management organizations and societies and pain patient advocacy groups. Taking a page from the tobacco industry, which had created and used front groups to proclaim tobacco was not harmful, Defendants harnessed and warped existing organizations to disseminate their deceptive messages with the expectation that these messages would circulate among and influence the conduct of prescribing physicians and other members of the medical community. These front organizations appeared to be legitimate scientific and patient advocacy organizations (and perhaps started out as such) and publicized seemingly scientific, balanced, and accurate information on opioid use. In fact, the information was false and misleading and paid for and encouraged by Defendants for creating a vast market for the use of opioids for chronic non-cancer pain.

152. The role of these organizations in promoting opioid use and their ties to opioid makers was highlighted when, on May 8, 2012, Senators Grassley and Baucus wrote to a half-dozen of these organizations:

> There is a growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic [of opioid use and abuse] by promoting misleading information about the

[49] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), http://online.wsj.com/news/articles/SB10001424127887324473830457817334265704460 4

> drugs' safety and effectiveness. Recent investigative reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica* revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the Academy of Pain Medicine, the Federation of State Medical Boards, the University of Wisconsin Pain and Policy Study Group, and the Joint Commission.
>
> In a ProPublica story published in the *Washington Post*, the watchdog organization examined the American Pain Foundation, a "health advocacy" organization that received "nearly 90 percent of its $5 million funding from the drug and medical device industry."[50] *ProPublica* wrote that its review of the American Pain Foundation's "guides for patients, journalists, and policymakers plays down the risks associated with opioids and exaggerate their benefits. "Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research.
>
> According to the *Milwaukee Journal Sentinel/MedPage Today*, a "network of national organizations and researchers with financial connections to the makers of narcotic painkillers . . . helped create a body of dubious information" favoring opioids "that can be found in prescribing guidelines, patient litigators, position statements, books and doctor education courses."[51]

153. These front groups, aided by millions of dollars in grants from Defendants and assistance from public relations firms hired by Defendants, spread the misrepresentation central to Defendants' fraudulent promotion of opioids. Indeed, Defendants influenced, if not outright controlled the messages disseminated by many of these front groups, including the American Pain Foundation ("APF") and the American Academy of Pain Medicine, ("AAPM").

[50] Charles Ornstein & Tracy Webber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011), http://www.probublica.org/article/the-champion-of-painkillers.
[51] John Fauber, *Follow the Money: Pain, Policy, and Profit*, Milwaukee Journal Sentinel/MedPage Today (Feb. 19, 2012), http://medpagetoday.com./Neurology.PainManagement/31256.

C(3). Method 3: Treatment Guidelines

154. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are otherwise not experts in, nor trained in, the treatment of chronic non-cancer pain. Treatment guidelines used in making treatment decisions are cited throughout the scientific literature and are referenced by third-party payers in determining whether they should cover treatments for specific indications.

155. In 2009, AAPM together with APS, issued the *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-cancer Pain.* The Guidelines represented a marked departure from previous guidelines for the promotion of opioids. The APS/AAPM guidelines promote opioids as "safe and effective" for treating chronic non-cancer pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients with and without past abuse histories. One member of the panel, Dr. Joel Sapr, Clinical Professor of Neurology at Michigan State University and the founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions by Defendants to the sponsoring organizations and committee members. These guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but the body of scientific evidence on opioids; the APS/AAPM guidelines have been cited 732 times in academic literature that, upon information and

belief, was disseminated in JEFFERSON County during the relevant time period, are still available on the internet, and were reprinted in the *Journal of Pain*.

156. In 2009, the American Geriatric Society ("AGS") revised its guidelines for the *Pharmacological management of Persistent Pain in Older Persons.* These guidelines included the following recommendations:

a) "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)."

b) "[Th]e risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."

These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence.

157. According to one news reports, AGS received $344,000.00 in funding from opioid makers since 2009.[52] Five of 10 experts on the guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock.[53]

158. In contrast, treatment guidelines that did not receive industry backing are much more reserved and endorse chronic opioid therapy only in narrow circumstances. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*,

[52] John Fauber and Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee Journal Sentinel/MedPage Today (May 30, 2012), http://medpagetoday.com/Geriatrics.PainManagement/32967.
[53] The Institute of Medicine recommends that, to ensure an unbiased result, that fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

issued by the American Society of Interventional Pain Physicians, included a disclaimer that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may in fact be facilitating it." The American Society of Interventional Pain Physicians Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, bus is in fact associated with serious health risks, including multiple fatalities and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." They recommend long-acting opioids in high doses only "in specific circumstances with severe intractable pain . . . with continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."

159. Similarly, the 2011 *Guidelines for Chronic Use of Opioids,* issued by the American College of Occupational and Environmental Medicine, recommended against "routine use of opioids for treatment of chronic pain patients," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.

160. Industry supported guidelines, in contrast, separate the strength of the recommendation from the strength of evidence supporting the recommendation. For instance, most of the "strong" recommendations of the APS/AAPM guidelines are backed

by only what the guidelines describes as weak evidence. Further, the guidelines Defendants supported fail to adequately take into account the potential adverse effects and specific label warnings that a physician should take into consideration in deciding on a treatment for any medical condition. As a result, they present a distorted picture of treatment options.

161. The separation of recommendations from the strength of supporting evidence proved useful for drug companies in promoting their opioids individually. Upon information and belief, the guidelines were widely referenced and promoted by the drug companies and their KOLs and front groups without disclosing the acknowledged lack of evidence to support them. This dangerously misrepresented to doctors the credibility and applicability of the pro-opioid recommendations.

C(4). Method 4: Continuing Medical Education

162. The millions of doctors and other health care professionals[54] who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. Defendants have sponsored thousands of CME programs that promote chronic opioid therapy and support and disseminate the deceptive and biased messages described in this Complaint. Upon information and belief, Defendants' grant making to fund and sponsor CMEs has been influenced by their marketing strategies and harnessed to the goal of increasing opioid sales. Upon information and belief, Defendants are more

[54] Lisa M. Schwartz & Steven Woloshin, *Medical Communication Companies and Continuing Medical Education: Clouding the Sunshine,* 310(23) The Journal of the Am. Med. Ass'n 2507, 2507 (Dec. 18, 2013).

than passive funders of these programs, which reached tens of thousands of doctors; they have influenced, if not outright controlled, the messages on topics and in the fields of practice Defendants targeted.

163. The American Medical Association has recognized that support from drug companies with financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.[55]

164. Defendants have long-standing relationships with the professional associations, advocacy organizations, presenters, and CME development companies that select and develop opioid related CMEs. These other organizations have depended upon Defendants' financial support for their activities and, in some cases, their very existence. It stands to reason that each of these organizations and the individuals running them know and believe that future financial support from Defendants depends upon producing programs that support the use of Defendants' products.

165. Defendants are able to influence – and even control – CLEs because they fund: (1) the KOLs who serve on the program committees of the professional societies that select the presentations and speakers and promote the views on which the

[55] *Opinion 9.0115 – Financial Relationships with Indus. in CME*, Am. Med. Ass'n (Nov. 2011), http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion90115.page.

presentations rely; (2) the KOLs who serve as speakers for the CME; and (3) the professional societies that host the conferences at which the presentations are given. Upon information and belief, many of these programs focus exclusively on prescribing opioids, and do not fairly present reasonable alternative treatments (except to discount them), nor do they fairly present (or present at all) the risks or benefits of chronic opioid therapy, nor how to take patients off opioids, once prescribed.

166. Defendants' sales representatives participated in conferences at which the CMEs were presented, encouraged doctors to attend the programs, and held auxiliary events that reinforced and amplified the distorted messaging of the CMEs. The CMEs themselves, however, buttressed by printed disclaimers by Defendants, were marketed to appear evidence-based and unbiased. In fact, like KOLs the CMEs are particularly effective for disseminating Defendants' messages because doctors rely on these peer-led professional events to deepen their understanding of clinical issues.

167. *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*, a CME program sponsored in part by Purdue and edited by KOL Dr. Perry Fine, provides one example of Defendants' use of CMEs to spread deceptive messages supportive of chronic opioid therapy. *Path of the Patien*t aimed to educate primary care doctors about managing chronic non-cancer pain with opioids. The presentation is devoted entirely to opioid prescribing and, despite its title, presents no other potential treatments. Far from a therapy of last resort, as conventional medical thought advised, *Path of the Patient* promotes opioid therapy as the only solution, even for common

chronic non-cancer pain issues such as back pain. This CME was available on-line to physicians, including those in Jefferson County, during the relevant time period.

168. In a role play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone polls a day as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of drug and alcohol abuse. Even given these facts, an authoritative narrator notes that, because of a condition known as pseudoaddiction, the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role play treats this patient by prescribing a high-dose, long-acting opioid.

169. An Endo-sponsored CME put on by the APF's national Initiative for Pain Control, *Persistent Pain in the Older Adult*, similarly reprises several of Defendants' misrepresentations. The program was first made available on-line in 2011, including to physicians in Jefferson County, and continued to be offered during the relevant time-period. The CME describes fear of addiction, safe use, and drug-drug interactions – all factors relating to addiction, abuse, and overdose – as the most significant barriers to treating "persistent" or chronic non-cancer pain in the elderly. The presentation counsels that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). Citing the AGS's treatment guidelines as its sole support, the CME describes the "chronic use of opioids in older adults" as "effective" and notes "possibly less potential for abuse than in younger patients." Its listed adverse outcomes simply omit

addiction, overdose, respiratory depression, or death, among others, and the slides note that tolerance to opioids' more mild side effects (such as dizziness or nausea) "develops within days to weeks." The CME never discloses the heightened risks opioids pose to elderly patients.

170. Dozens of CMEs that were available during the relevant time period and continue to be available to doctors in Jefferson County during the relevant time period also promoted the false concepts that opioids improve quality of life and physical function, that the risk of addiction to opioids is low, and that doctors can identify and manage patients at higher risk of addiction. The programs train doctors to use specific risk training tools without disclosing that the tools are unproven or that the lack of evidence that high-risk – or any –patients can take opioids long term without becoming addicted.

C(5). Method 5: Scientific Articles

171. Defendants rely on misleading and deceptive citation of scientific articles to overstate the benefits of chronic opioid therapy and minimize its serious risk and fail to disclose contrary evidence. For instance, the Purdue-funded *Policymaker's Guide* (2011) makes the particularly callous representation that less than 1% of children prescribed opioids will become addicted. In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain. The purpose of the *Guide* was to support opioid therapy generally; it was not focused on or restricted to cancer pain – patients – the only population addressed in Dr. Foley's article, which also did not reference pediatric cancer patients or include <u>any</u> statistics on addiction rates. Purdue

funded and distributed the *Guide* with this misleading citation, knowing that there was no evidence to support the general assertion that children will not become addicted to opioids, even when taken long-term. Upon information and belief, the *Guide* was distributed in Jefferson County during the relevant time period.

172. Similarly, a 2003 scientific study funded by Purdue and co-authored by a Purdue employee concluded that OxyContin is "effective and safe for the management of [chronic diabetes-related pain] and improves QOL [quality of life]." The study asserts that there is "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse." The authors cite a single article by Porter and Jick, *Addiction Rare in Patients Treated with Narcotics*, published in the prestigious New England Journal of Medicine. What the authors fail to disclose is that the "evidence" is actually a letter to the editor, not a peer reviewed article. Moreover, the letter describes not a study but a chart review of hospitalized patients; if medical charts failed to note that the patients exhibited documented signs of addiction while on opioids, the authors concluded that they were not addicted. Not only did the study not support the authors' assertion, but the authors' misleading citation of it created a false impression of its reliability. The Porter and Jick letter and the 2003 Purdue study have been cited 810 and 455, respectively, in the medical literature since 2008.

173. Practicing doctors, particularly the busy family doctors and general practitioners targeted by Defendants, do not have time to look behind seemingly authoritative sources, particularly in scientific literature. They do – and must be able to – rely on citations to scientific literature, a fact that Defendants use to their advantage.

Moreover, the misleading use of studies to give them weight or meaning they do not have is like a virus; once embedded in the literature, it takes on a life of its own. Studies that assert addiction is rare, relying either on the Foley or Porter-Jick analyses, themselves are cited for the proposition. Thus, with a few key manipulations and deceptive citations, Defendants were able to seed a scientific consensus supportive of chronic opioid therapy.

C(6). Method 6: Patient Education

174. Defendants reach chronic non-cancer pain patients through written publications, websites, and videos designed to present the purported "facts" about opioids in a simple, user-friendly manner. As Defendants know, these materials are accessed by both patients doing their own research and doctors, who read them when distributing them to patients. The materials Defendants produced concerning opioids include numerous fraudulent representation, overstate the benefits of chronic opioid therapy, and fail to fully disclose its risks, particularly the risks of addiction.

175. The pamphlet, *Finding Relief: Pain Management for Older Adults* (2009) describes opioids as "rarely addicting when used properly for the management of chronic pain" and assures that "unless the underlying cause of your pain gets worse . . . you will probably remain on the same dose or only need small increases over time." As described, *supra,* these contentions are wholly lacking in scientific or clinical support.

176. Defendants created campaigns – including literature, websites, community groups, and programs – related to chronic non-cancer pain from illnesses such as lower back pain, shingles, migraines, osteoarthritis, phantom limb pain, fibromyalgia, and multiple sclerosis. These conditions affect significant numbers of people who have

formed affinity groups and online communities for support in seeking to address conditions that produce persistent pain and may necessitate long-term treatment. Defendants used this community-building to promote the use of opioids in the treatment of these conditions, despite the fact that there was little or no scientific evidence supporting the use of opioids for these conditions, and little or no evidence supporting or even suggesting that the use of opioids for these conditions would provide more benefit from pain relief than harm from the many known and significant opioid treatment risks. None of these conditions reflect indications approved to appear on Defendants' drug labels, supporting the inference that Defendants did not have evidence to obtain such approval.

177. In addition to their general marketing efforts, Defendants made special efforts to market to two particularly vulnerable patient groups: the elderly and veterans. While obvious markets for chronic non-cancer pain medications, each of these patient populations has risk factors that make long-term opioid use particularly dangerous.

178. Elderly patients taking opioids have been found to suffer elevated fracture risks, a greater risk for hospitalization, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression.[56] A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.[57] Defendants

[56] Kathleen W. Sanders et al., *Relationship of opioid se and dosage levels to fractures in older chronic pain patients*, 25 (4) Journal of Gen. Internal Med., 310-315 (Apr. 2010).
[57] Daniel H. Solomon et al., *The Comparative Safety of Analgesics in Older Adults with Arthritis*, 170(22) Archives of Internal Med., 1968-1976 (Dec. 13, 2010).

targeted marketing to the elderly and the absence of cautionary language in its promotional materials flies in the face of scientific evidence and even their own labels and creates a heightened risk of serious injury.

179. In their effort to reach elderly patients who have pain associated with arthritis and other aging-related conditions, Defendants' education materials focused on elderly patients. *Finding Relief: Pain Management for Older Adults*, a 2009 publication sponsored by Janssen, repeated the same, unsubstantiated, deceptive statements that opioids are "rarely addictive" and increase patients' function.

180. Likewise, the Defendants targeted vulnerable veterans with opioid marketing. Opioids are particularly dangerous to veterans. According to a study published last year in the Journal of American Medicine, veterans returning from Iraq and Afghanistan prescribed opioids have higher incidence of adverse clinical outcomes, like overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death.[58] Yet, according to a Veterans Affairs Office of Inspector General Report, 92.6% of veterans chronically prescribed opioids were also prescribed benzodiazepines.[59]

[58] Karen H. Seal et al., *Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan,* 307(9) The Journal of the Am. Med. Ass'n, 940-947 (Mar. 7, 2012).

[59] Bill Briggs, *VA Docs Defied Opiate Rules in Treating Vets, Audit Finds*, NBC News (May 15, 2014), http://nbcnew.com/storyline/ca-hospital-scandal/va-docs-defied-opiate-rules-treating-vetspaudit-finds-n106461.

181. Purdue sponsored APF's *Exit Wounds: A Survival Guide* (2009), a book available from Amazon.com and other retailers. *Exit Wounds* is aimed at veterans. *Exit Wounds* bills itself as a survival guide to pain management for returning veterans and their families. The book describes opioids as "under-used" and the "gold standard of pain medications" and further states that veterans not predisposed to addiction are very unlikely to become addicted. The book also asserts that "denying a person opioid pain medications because he or she has a history of substance abuse or addiction is invalid and contrary to the guidelines for the prescription of opioids published by the U.S. Federation of State Medical Boards." Importantly, the U.S. Federation of State Medical Boards received support from Defendants during the time it created and published its guidelines for prescription of opioids. This book omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines.

182. A 2008 survey showed prescription drug abuse among military personnel doubled from 2002 to 2005 and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills – four times as many as they did in 2001.[60] Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days.[61] Although, upon information and belief, many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far

[60] *Id.*
[61] American-Statesman Investigative Team, *Prescription drug abuse, overdoses haunt veterans seeking relief from physical, mental pain,* Austin American-Statesman (Sept. 29, 2012).

too many cases, unsuited for their treatment. Among former service members receiving Veterans' Administration services nationally in a single year (2005), 1,013 died of accidental drug overdoses – double the rate of the civilian population. The Martinsburg Veterans Administration Center in Berkeley County, which upon information and belief, serves residents of Jefferson County, regularly prescribes opioids to veterans.

D. Defendants Often Acted Together in Promoting Opioids, Opposing Regulation, and Otherwise Clearing the Way for the Increased Prescription and Distribution of Opioids.

183. Working in concert and individually, Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Defendants needed to generate this comfort level among doctors and patients to ensure patients were maintained on the drugs.

184. As explained above, Defendants supported, assisted, encouraged, and/or facilitated the same front groups and KOLs to disseminate the same deceptive messages about the use of opioids to treat chronic non-cancer pain. In fact, the similarity of their messages, language, and even their formatting suggests that Defendants participated in a common scheme to disseminate misleading information about opioids.

185. This inference is supported by Defendants' cooperation in other activities to promote opioids, including successful efforts to set standards for measuring and treating pain, training and regulating doctors, and approving new opioids.

186. Defendants' efforts to shift the paradigm on opioids and pain treatment began soon after their branded opioids were launched. In 2000 the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), in conjunction with the University of Wisconsin Pain and Studies Group, declared that pain was the "5th Vital Sign" and required all healthcare practitioners to make pain assessment and management a priority in daily practice.

187. Upon information and belief, the impetus behind the new pain standard began with June Dahl, then a professor of pharmacology at the University of Wisconsin-Madison. Dr. Dahl approached JCAHO with a proposal and helped identify pain management experts and key organizations to act as advisors to JCAHO, as well as promoters of Pain as the 5th Vital Sign. Those experts and key organizations are many of the same heavily funded KOLs and front groups that ultimately helped bring about the change in attitudes toward opioids and, subsequently, the rise in the prescription of opioids. Defendant Purdue was one of two companies that paid for programs across the country to educate hospital physicians and staff about complying with the new pain standards and had exclusive rights to distribute certain education materials to JCAHO members.[62]

188. Once health practitioners were required to consider a patient's pain along with other vitals, the next step was to convince practitioners that all pain must be treated – preferably with opioids. In 2004, the Federation of State Medical Boards revised and

[62] *Prescription Drugs: OxyContin Abuse & Diversion & Efforts to Address the Problem,* U.S. Gen. Accounting Office (Jan. 22, 2004), www.gao.gov/htext/d04110.html.

updated its Model Policy for the Use of Controlled Substances for the Treatment of Pain. In support of those efforts, noted KOL dr. Scott Fishman was tapped to author a companion piece, titled *Responsible Opioid Prescribing: A Physician's Guide* (2007).

189. The Guide was sponsored by Defendants Endo, and Purdue and was distributed to state medical boards, healthcare regulatory boards, medical organizations, hospitals, and physicians across the country, including in Jefferson County. The *Physician's Guide* contained many of the misrepresentations described above, notably, the concept of pseudoaddiction and the claim that opioids improve function.

190. Defendants also worked together to promote opioids through the Pain Care Forum. The Forum is comprised of representatives from opioid manufacturers and distributors (including each of the Defendants); doctors and nurses in the field of pain care; health care professional organizations (*e.g.*, American Academy of Pain Management, American pain Society, and American Society of Pain Educators); patient advocacy groups (*e.g.*, Federation of State Medical Boards and Wisconsin pain & policy Studies Group), almost all of which received substantial funding from Defendants. Upon information and belief, the Pain Care Forum was started, and continues to be run, by Defendant Purdue's in-house lobbyist Burt Rosen, previously in conjunction with APF.

191. Upon information and belief, the Defendants collaborated on a common campaign to build a market for opioids for chronic non-cancer pain, a market upon which they could all capitalize.

E. Defendants knew that their marketing of chronic opioid therapy was false, misleading, unfounded, and dangerous, yet they persisted in marketing the drugs for chronic non-cancer pain.

192. In addition to participating in a concerted campaign to expand the general market for opioids, each Manufacturer Defendant acted on its own to deceptively market its specific branded drugs and to capture a larger share of the chronic non-cancer pain market. Separately, in their branded materials and on "front" websites, each manufacturer overstated the benefits and understated the risks of their specific drugs, often prompting formal admonishment from the FDA for dangerously false or misleading claims.

193. Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew their marketing was false and misleading. The FDA and other regulators warned Defendants of this, and Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to address nearly identical misconduct that occurred before 2008. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients were suffering from addiction, overdoses and death in alarming numbers. More recently, the FDA and CDS have issued pronouncements based on existing medical evidence that conclusively expose the known falsity of Defendants' misrepresentations.

194. Moreover, Defendants intended doctors, patients, and payers to rely on their representations. Defendants closely monitored their sales and the habits of prescribing doctors, which allowed them to see sales balloon, overall, in individual

practices, and for specific indications. Sales representatives who visited doctors and attended CMEs knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to and also watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew and, indeed, intended – that their misrepresentations would persuade doctors to prescribe, patients to use, and payers to cover prescriptions of opioids for chronic pain.

195. Notwithstanding this knowledge, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional association. Purdue, Endo, Cephalon, and Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue, Endo, Cephalon, and Janssen masked or never disclosed their role in shaping, editing, and approving the content of this information. Defendants also distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support.

196. Upon information and belief, while the Manufacturer Defendants were listed as sponsors of many of the publications listed in this Complaint, they never disclosed their role in shaping and editing the content of those publications. Further, upon

information and belief, Defendants exerted their considerable influence on these promotional and "educational" materials through their funding of and relationship with KOLs and front groups, both directly and through their public relations companies.

197. Contrary to their competitive interest in promoting their own opioid products, Defendants disseminated their deceptive messages through websites that were unbranded and therefore could not easily be tied to a particular drug company sponsor. This unbranded messaging created the appearance of neutrality and gave Defendants' marketing messages the appearance of unbiased medical science.

198. Upon information and belief, Defendants also obscured their participation by extensively using the public relations companies they hired to work with front groups to produce and disseminate deceptive materials.

199. Further, in addition to hiding their own role in the deceptive conduct, the manufacturer Defendants manipulated their promotional materials to make it appear that they were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The true lack of support for Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions. Only recently have some of the KOLs whom Defendants relied upon and promoted to spread their deceptive messages begun to acknowledge the lack of support for their positions.

200. Thus, while the opioid epidemic in Jefferson County and across the nation was increasingly evident, Defendants, in furtherance of their marketing strategy,

intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that the County Commission now asserts. The Commission was not alerted to the existence and scope of Defendants industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through their public statements, marketing, and advertising, Defendants' deceptions deprived the City of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

F. Defendants continued to tell doctors that opioids could be taken in ever-higher doses without disclosing their greater risks.

201. Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Defendants needed to generate this comfort level among doctors and patients to ensure patients were maintained on the drugs. Further, as described in more detail *infra*, Purdue encouraged doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice-a-day – despite knowing that OxyContin frequently did not provide 12 hours of relief.

202. Purdue-sponsored publications and CMEs available in New Jersey also misleadingly suggested that higher opioid doses carried no added risk.

203. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

204. *A Policymaker's Guide*, the 2011publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are "sometimes necessary," but did not disclose the risks from high dose opioids. This publication is still available online.[63]

205. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

206. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which contained a Q&A section that asked, "If I take the opioid now, will it work later when I really need it?" The response was, "The dose can be increased . . . You won't 'run out' of pain relief."

207. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its sales force distributed. This guide listed dosage limitations as "disadvantages" of other pain medicines, but omitted any discussion of risks of increased opioid dosages.

208. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per

[63] *See* note 33 *supra*.

day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses.[64] As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

209. The CDS Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[65] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[66]

G. Purdue misleadingly promoted OxyContin as supplying 12 hours of pain relief when it knew that for many patients, it did not.

210. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch. While OxyContin's FDA-approved label directs 12-hour dosing, Purdue sought that dosing frequency in order to maintain a competitive

[64] Kate M. Dunn, *et al.*, *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152(2) Annals of Internal Med. 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal.
[65] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.
[66] CDC Guideline at 16.

advantage over more frequently dosed opioids. Yet Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours by affirmatively claiming, in their general marketing and upon information and belief, to prescribers in the City, that OxyContin lasts for 12 hours, promoting 12-hour dosing as a key advantage of OxyContin, and by failing to disclose that OxyContin fails to provide 12 hours of pain relief to many patients.

211. These misrepresentation, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below. Purdue conveyed to prescribers that the solution to end-of-dose failure is not more frequent dosing, but higher doses, which pose greater risks.

212. OxyContin has been FDA-approved for twice-daily – Q12 – dosing frequency since its debut in 1996, yet it was Purdue's decision to submit OxyContin for approval with 12-hour rather than 8-hour dosing.

213. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," Purdue has conducted no such studies.

214. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But

the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure" – i.e., little or no pain relief at the end of the dosing period.

215. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers – "rescue medication" – in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

216. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose – a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[67] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

[67] Harriet Ryan, "'*You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

217. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours) because 12-hour dosing was "a significant competitive advantage." Purdue also falsely promoted OxyContin as providing "steady state" relief, less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse – a misrepresentation made upon information and belief, in Jefferson County.

218. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading, because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing, to disclose to prescribers what it knew about OxyContin's actual duration, and not to promote more dangerous higher dosing, rather than increased frequency of use, regardless of any marketing advantage.[68]

219. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours – a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency of

[68] Kadian, an opioid manufactured by Allergan, was designed to be taken once a day, but the label acknowledges and advises dosing of up to every 12 hours for certain patients.

prescriptions, even though higher dosing carries its own risks – including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on analysis by the Los Angeles Times, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day – which converts to the 90 mg MED equivalent that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[69]

H. Purdue and Endo overstated the efficacy of abuse-deterrent opioid formulations.

220. By the mid-200's, widespread addiction to and abuse of OxyContin had emerged in the public eye. Rather than acknowledge that these problems were the inevitable result of widespread prescribing of OxyContin for chronic pain, Purdue claimed that abuse and addiction resulted from diversion by abusers snorting or injecting the drugs. Purdue also brought to market an "abuse-deterrent" formulation of OxyContin but deceptively marketed it to doctors as a solution to the opioid epidemic.

221. Reformulated, ADF OxyContin was approved by the FDA in April 2010. However, the FDA noted that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties.

[69] CDC Guideline at 16.

222. Purdue sales representative regularly used the so-called abuse-deterrent properties of Purdue's opioid as a primary selling point to differentiate those products from their competitors, including, upon information and belief, in JEFFERSON County. Specifically, Purdue detailers:

a) claimed that Purdue's ADF opioids *prevent* tampering and that its AD products could not be crushed or snorted;

b) claimed that Purdue's ADF opioids *reduce* opioid abuse and diversion;

c) asserted or suggested that Purdue's ADF opioids are "safer" than other opioids; and failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

223. These statements and omissions by Purdue are false and misleading and are inconsistent with the FDA-approved labels for Purdue's ADF opioids – which indicate: that abusers seek them because of their high likeability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties, and which do not indicate that ADF opioids prevent or reduce abuse, misuse, or diversion,

224. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[70] and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit

[70] *In re OxyContin*, 1:04-md-01603-SHS, Docket No 613, Oct. 7, 2013 Hr'g, Testimony of Dr. Mohan Rao, 1615:7-10.

juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare OxyContin to be snorted or injected.

225. Further, one-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, those addicts simply shifted to other drugs such as heroin.

226. A 2013 article presented by Purdue employees based on review of data from poison control centers, while concluding that ADF OxyContin can reduce abuse, ignored important negative findings. The study reveals that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculates, there were **more** harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article emphasized the advantages and ignored the disadvantages of ADF OxyContin – reflecting the same pattern of tilting scientific research and literature to support the promotion of opioids.

227. The CDC Guideline confirms that "[*n*]*o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."[71] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence

[71] CDC Guideline at 22 (emphasis added).

showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."[72]

228. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[73] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

229. Yet despite the qualifying language in Purdue's label and its own evidence – and lack of evidence – regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.

230. Generic versions of OxyContin, which became available in February 2011, threatened to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013,

[72] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution,* Assoc. Press (Jan. 2, 2017), http://detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.
[73] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory committee and the Anesthetic and Analgesic Drug Products Advisory Committee, Notice of Meeting, May 25, 2015, 80 RF 30686,

that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

231. Purdue's false and misleading marketing of the benefits of its ADG opioids preserved and expanded its sales by persuading doctors to write prescriptions for ADF opioids in the mistaken belief that they were safer. It also allowed prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids – *i.e.*, it allowed them to believe that while patients might abuse, become addicted to, or die from other, non-ADF opioids, Purdue's opioids did not carry that risk.

232. Endo has marketed Opana ER as tamper- or crush-resistant and less prone to misuse and abuse since at least May 21, 2011, even though: (1) the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. And since 2012, detailers for Endo have informed doctors, including, upon information and belief, doctors in JEFFERSON County, that Opana ER was harder to abuse. A consumer survey further confirms several prescribers in the northeastern United States confirming that Endo sales representative promoted Opana ER as "crush resistant."

233. In a 2016 settlement with Endo, the New York Attorney General ("NY AG") found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AC also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

V. FACTUAL ALLEGATIONS – DISTRIBUTOR DEFENDANTS

A. The Distributor Defendants had an affirmative duty to monitor the number of doses they distributed into Berkeley County.

234. The Manufacturer Defendants share responsibility for the rampant opioid epidemic with another group of actors, the Wholesale Distributors of prescription opioid medications. Rarely do manufacturers sell opioid medicines – or any other prescription medicine – directly to the end user of the drug. Instead, manufacturers sell opioids to wholesale distributors who then sell the drugs to pharmacies and other health care providers at cost plus a negotiated markup percentage.[74] The Distributor Defendants are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is

[74] The Health Strategies Consultancy, LLC, *Follow the Pill: Understanding the U.C. Commercial Pharmaceutical Supply Chain* (March 2005), http://avalere.com/research/docs/Follow_the_Pill.pdf.

critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[75]

235. Each Distributor Manufacturer has an affirmative duty under federal and West Virginia law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. The federal Controlled Substances Act ("CSA") requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§812(b)(1).

236. The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.

237. The CSA authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market. H.R. Rep. No. 91-1444,

[75] *See* U.S. Department of Justice, Drug Enforcement Administration, letter to Cardinal Health dated September 27, 2006 ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.") (a copy of letter is filed at *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-5, filed therein in U.S. D.C. on February 20, 2012)).

1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970), *see* 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880. Any entity that seeks to become involved in the production or chain of distribution of controlled substances must first register with the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

238. The CSA provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal. 1970 U.S.C.C.A.N. 4566, 4569.

239. "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975).

240. Distributors of Schedule II drugs – controlled substances with a "high potential for abuse," 21 U.S.C. §§ 812(b), 812(2)(A)-(C) – must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels," *Id.* § 823(b)(1). In addition, distributors that supply controlled substances to pharmacies must "design and operate a system to disclose to the [distributor] suspiscious orders of controlled substances" and, in turn, disclose those suspicious orders to the DEA. 21 C.F.R. § 1301.74(b). "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of

unusual frequency." *Cardinal Health, Inc. v. Holder*, 846 F. Supp.2d 203, 206-07 (D.D.C. 2012).

241. The CSA is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. **Such a closed system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market,** while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. 1970 U.S.C.C.A.N. 4566, 4571-72.

242. "Suspicious orders" include orders of an unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.[76]

[76] *See* U.S. Department of Justice, DEA letter to Cardinal Health dated December 27, 2007, note 62 *supra.*

243. The closed system of the CSA is specifically designed with checks and balances between registrants to ensure that controlled substances are not diverted from this closed system.[77]

244. The CSA seeks, through appropriate regulation of the manufacture and distribution of drugs, to reduce the availability of drugs subject to abuse except through legitimate channels of trade and for legitimate uses. 1970 U.S.C.C.A.N. 4566, 4574.

245. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations carefully define each participant's role and responsibilities.[78]

246. **Federal law imposes a duty upon the Distributor Defendants to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels**. 21 U.S.C. § 823(b)(1).

247. **Federal law imposes a duty upon the Distributor Defendants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."** 21 CFR 13.01.74(b).

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[77] *See* Declaration of Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Agency, United States Department of Justice, ¶ 8, *Cardinal Health, Inc. v. Holder*, 846 F. Supp.2d 203, 2021 WL 11747342 (US Dist. DC 2012).

[78] *See* Brief for Healthcare Distribution Management Association ("HDMA") and National Association of Chain Drug Stores ("NACDS") as *Amici Curiae* in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983, 10 (C.A.D.C.)(April 4, 2016).

248. Federal law imposes a duty upon the Distributor Defendants to comply with applicable State and local law. 21 U.S.C. § 823(b)(2).

249. The West Virginia Legislature enacted the West Virginia Wholesale Drug Distribution Licensing Act of 1991, W. Va. Code § 60A-8-1 *et seq.* [1991], to protect the health, safety, and general welfare of residents of this state and authorized that the board of pharmacy should promulgate rules to carry out its purpose.

250. **West Virginia state law imposes a duty on the Distributor Defendants to provide effective controls and procedures to guard against theft and diversion of controlled substances.** 15 CSR 2-4.2.1.

251. **West Virginia state law imposes a duty upon the Distributor Defendants to design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the West Virginia Board of Pharmacy of suspicious orders when discovered. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.** 15 CSR 2-4.4.

252. **Distributor Defendants have a duty to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels.** *Cardinal Health, Inc. v. Holder*, 846 F. Dupp.2d 203, 206 (D.D.C. 2012).

253. These duties are well known to the Distributor Defendants. "DEA regulations that have been in place for more than 40 years require distributors to report

suspicious orders of controlled substances to DEA based on information readily available to them (*e.g.*, a pharmacy's placement of unusually frequent or large orders)."[79]

254. The DEA has ensured that the Distributor Defendants understand the scope of this duty. The DEA has provided briefings to each of the Distributor Defendants and conducted a variety of conferences regarding their duties under federal law. Further, the DEA sent a letter to each of the Distributor Defendants on September 26, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[80]

255. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007. This letter reminds the Distributor Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order

[79] *See* Brief for HDMA and NACDS, 4, *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*
[80] DEA Letter September 27, 2006.

report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the pattern throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more that is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be

> failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion in inconsistent with the public interest as that term is used in 21 U.S.C. 823 and 834, and may result in the revocation of the registrant's DEA Certificate of Registration.[81]

256. The Distributor Defendants "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[82]

257. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain the distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.

258. Here, each of the Distributor Defendants is registered with the DEA as a distributor in the chain of distribution of Schedule II controlled substances and has

[81] DEA Letter dated December 27, 2007.
[82] *See* Brief for HDMA and NACDS, 4 *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, *Amicus Curiae* Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, 2012 WL 1637016, *2 (C.A.D.C.) (May 9, 2012).

therefore assumed the duties imposed under the CSA. Further, each of the Distributor Defendants is a "registrant" as a distributor in the chain of distribution of Schedule II controlled substances and assumed the security requirement duties imposed under the regulations adopted by the West Virginia Board of Pharmacy.

259. Each of the Distributor Defendants sold prescription opiates to retailers in Jefferson County, West Virginia, and therefore had an affirmative duty under federal and West Virginia law to guard against the diversion of opioid drugs in that community.

B. The Distributor Defendants deliberately, knowingly, and for profit, breached their duties.

260. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[83]

261. The Distributor Defendants are required to report the sale of all prescription opiates, including those sold to pharmacies in Jefferson County, to the Automation of Reports and Consolidated Orders System ("ARCOS") database. *United States v. Four Hundred Sixty Three Thousand Four Hundred Ninety Seven Dollars & Seventy Two Cents ($463,497.72) in U.S. Currency From Best Bank Account*, 779 F.Supp.2d 696, 709 (E.D. Mich. 2011).

[83] *See* Declaration of Joseph Rannazzisi, Deputy Administrator, Office of Diversion Control, Drug Enforcement Agency, United States Department of Justice, ¶ 10, *Cardinal Health, Inc., v. Holder,* No. 1:12-cv-00185-RBW, Doc. 14-2 (filed in U.S. on February 20, 2012).

262. The DEA has disclosed to the West Virginia Attorney General certain data from the ARCOS database relating to the sale of hydrocodone and oxycodone doses to retailers in West Virginia between 2007 and 2012. This information has become public knowledge as reported by the Charleston Gazette and reveals that drug wholesalers sold West Virginia pharmacies 780 million hydrocodone and oxycodone pills during this timeframe.[84] The records also document the number of prescription opiates sold to each of the 55 counties in West Virginia between 2007 and 2012.

263. To put these numbers into perspective, the United States consumes opioid pain relievers ("OPR") at a greater rate than any other nation. West Virginia has an OPR prescription rate of 137.6 per 100 persons which ranks 3rd in the country (U.S. average rate: 82.5) and a benzodiazepine prescription rate of 71.9 per 100 persons, which ranks 1st nationally (U.S. average rate 37.6).[85]

264. The sheer volume of prescription opioids distributed in West Virginia in general and Jefferson County in particular is so excessive for the medical needs of the community as to be facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them. *See Masters Pharmaceuticals, Inc.: Decision and Order,* 80 FR 55418-01, 55482 (Sept. 15, 2015) (*citing Holiday CVS, LLC, d/b/a CVS/Pharmacy Nos.*

[84] *See* Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses,* Charleston Gazette (Dec. 17, 2016).

[85] The combination of hydrocodone, oxycodone, and benzodiazepines is referred to as the "holy trinity" and significantly increases the risk of harm to those that abuse prescription pills. *See* Leonard J. Paulozzi, MD et al., *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012,* Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (July 4, 2014).

219 and 5195, 77 FR 62,316, 62,322 (2012)); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017).

265. Plaintiff Jefferson County Commission has information and believes that the Distributor Defendants failed to report any "suspicious orders" originating from Jefferson County to the DEA and/or the West Virginia Board of Pharmacy between 2007 and 2012. Instead, the Distributor Defendants unlawfully filled suspicious orders of unusual size and frequency, orders deviating substantially from a normal pattern in Jefferson County.

266. The federal and state statutes the Distributor Defendants breached, 21 U.S.C. § 823(b)(1), 21 C.F.R. 1301.74(b), 15 C.S.R. 2-4.2.1 and 15 C.S.R. 2-4.4, are public safety statutes.

267. Each Distributor Defendant breached its duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels in violation of 21 U.S.C. § 823(b)(1).

268. Each Distributor Defendant breached its duty to "design and operate a system to disclose the registrant suspicious orders of controlled substances" and failed to inform the DEA of "suspicious orders when discovered" in violation of 21 C.F.R. 1301.74(b).

269. Each Distributor Defendant breached its duty to provide effective controls and procedures to guard against theft and diversion of controlled substances in violation of 15 C.S.R. 2-4.2.1.

270. Each Distributor Defendant breached its duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the West Virginia Board of Pharmacy of suspicious orders when discovered" in violation of 15 C.S.R. 2-4.4.

271. Distributor Defendants' violations of public safety statutes constitute *prima facie evidence* of negligence under West Virginia law.

272. **Distributor Defendants breached their duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates originating from Jefferson County, West Virginia.**

273. The unlawful conduct by the Distributor Defendants is purposeful and intentional. Bluntly, they refuse to abide by the duties imposed by law which are required to maintain a DEA registration to distribute prescription opiates.

274. Distributor Defendants breeched their duty to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Jefferson County or which Defendants knew of should have known were likely to be delivered and/or diverted into Jefferson County.

275. In fact, Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In *Maters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983 (C.A.D.C.) (April 4, 2016), the Healthcare Distribution Management Association and National Association of Chain Drug Stores submitted *amicus* briefs regarding the legal duty of wholesale distributors under the CSA. They argued:

a) The "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (*e.g.*, by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled. Those added obligations would significantly expand the "report-only" duty of distributors under the longstanding regulatory scheme and impose impractical obligations on distributors, which occupy a fundamentally different position than the physicians who prescribe the drugs to patients or pharmacists who dispense drugs to fill those prescriptions;[86]

b) The DEA now appears to have changed its position to require that distributors not only report suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation of distributors threatens to disrupt patient access to needed prescription medications;[87]

c) Nothing in Sections 1301.72-1301.76 requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious;[88]

d) The practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties;[89]

e) DEA's regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders;[90]

f) There is simply no practical way for distributors to look over the shoulder of pharmacists and double-check the validity of each prescription in light of an individual patients' circumstances;[91]

g) Imposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with the DEA's demands;[92] and

h) Given the unique role that distributors occupy in the healthcare system, any attempt to impose additional obligations on them to investigate and halt suspicious

[86] HDM and NACDS Amicus Brief, *Masters Pharmaceuticals v. United States DEA*, No. 15-1335 (April 4, 2016) (emphasis in original).
[87] *Id.*, (internal citations omitted) (internal quotes omitted) (emphasis in original).
[88] *Id.*
[89] *Id.*
[90] *Id.* (emphasis in original).
[91] *Id.*
[92] *Id.*

orders would raise serious policy and practical issues, such as the disruption of patient access to prescribed medications.[93]

276. It should be noted that oral argument was held on January 12, 2017, before the Court of Appeals for the DC Circuit. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants regarding its duties under the CSA.[94] But "[i]gnorance of the law excuses no one." *State v. Ross*, 70 W. Va. 549, 74 S.E. 670, 674 (1912).

277. So, because of the Distributor Defendants' decades-long refusal to abide by federal law, the DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Division, reported that the DEA issue final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving order to show cause and 41 actions involving immediate suspension orders.[95] These actions include the following:

a) On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;

b) On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn Washington Distribution

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[93] *Id.*

[94] *See Amicus Curiae* Brief of HDMA, *Cardinal Health, Inc. v. United States Dept. Justice* (arguing the wholesale distributor industry "does not know the rules of the road" because they claim the "DEA has not adequately explained them.").

[95] *The Drug Enforcement Administration's Adjudication of Registrant Actions,* United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014).

Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c) On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d) On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e) On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f) On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 CFR § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g) On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia; Valencia, California, and Denver, Colorado;

h) On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;

i) On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j) On January 5, 2017, Mckesson Corporation entered into an *Administration Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.

278. Rather than abide by these public safety statutes, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Dept. of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension can be issued.[96]

279. Meanwhile, the opioid epidemic rages unabated in JEFFERSON County, West Virginia.

280. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the Distributor Defendants. They pay fines as a cost of doing business in an industry which generates billions of dollars in annual revenue. They hold multiple DEA registration numbers, and when one facility is suspended, they simply ship from another facility. And, as bluntly noted by Cardinal Health in its filings in *Cardinal Health, Inc. c. Holder*, 846 F. Supp.2d 203 (D.D.C. 2012), "suspension . . . will not address the harm DEA alleges because it will not prevent pharmacies filling

[96] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control*, The Washington Post (October 22, 2016); Lenny Bernstein & Scott Higham, *Investigation: U.S. senator calls for investigation of DEA enforcement slowdown amid opioid crisis*, The Washington Post (March 6, 2017); Eric Eyre, *DEA agent: 'We had no leadership' in WV amid flood of pain pills*, Charleston Gazetteer (February 18, 2017).

illegitimate prescriptions from simply obtaining controlled substances from another distributor."[97]

281. The Distributor Defendants have abandoned the duties imposed on them by federal and state law, taken advantage of a lack of DEA law enforcement in West Virginia and abused the privilege of distributing controlled substances in Jefferson County.

282. The Distributor Defendants' repeated shipments of suspicious orders over an extended period of time in violation of public safety statues without reporting those suspicious orders to the relevant authorities – including the DEA and the West Virginia Board of Pharmacy – demonstrates wanton, willful, or reckless conduct and criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

VI. FACTUAL ALLEGATIONS – ALL DEFENDANTS

A. The combined actions and omissions of the Manufacturer and Distributor Defendants has directly caused the increasingly widespread misuse of powerful opioid medications – including the heroin epidemic.

283. The Manufacture Defendants' misrepresentations prompted doctors to prescribe, patients to take, and payers to cover opioids for the treatment of chronic non-cancer pain, believing that the benefits outweighed the risks and were better than alternative treatments. Defendants set out to overcome barriers to widespread prescribing

[97] Memorandum of Points of Authorities in Support of Cardinal Health's Motion for Temporary Restraining Order (Doc. 3-1), at p. 22, *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.C. Cir. Feb. 3, 2012).

of opioids – and succeeded – through a series of deceptive messages designed to misrepresent the benefits, risks, and superiority of opioids over other treatments,

284. Defendants' deceptive marketing substantially contributed to an explosion in the use of opioids. Approximately 20% of the population between the ages of 30 and 44, nearly 30% of the population over 45 have used opioids.[98] Indeed, "[o]pioids are the most common means of treatment for chronic pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per year are prescribed a long-acting opioid."[99] A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010 even though the number of office visits in which patients complained of pain did not change; prescribing of non-opioid pain medications decreased over the same time.[100] For back pain alone – one of the most common chronic non-cancer pain conditions – the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady.[101] This increase corresponds with, and was caused by Defendants' marketing push.

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[98] Marie N. Stagnitti, *Statistical Brief #235: Trends in Outpatient Prescription Analgesics Utilization and Expenditures for the U.S. Civilian Noninstitutional Population, 1996 and 2006,* Agency for Healthcare Research and Quality, Fig. 6 (Feb. 2009), http://meps.ahrq.gov/mepsweb/dat_files/publications/st235/stat235.pdf.

[99] Deborah Grady et al., *Opioids for Chronic Pain,* 171(16) Archives of Internal Med. 1426, 1426 (Sept. 12, 2011).

[100] Matthew Daubresse et al., *Ambulatory Diagnosis & Treatment of Nonmalignant Pain in the U.S., 2000-2010,* 51(10) Med. Care, 870-878 (Oct. 2013).

[101] John M. Mafie et al., *Worsening Trends in the Mgmt. & Treatment of Back Pain,* 173(17) Journal of the Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

285. The Distributor Defendants responded to the increased demand for opioid medications by filling and shipping orders with little or no regard for their duties to monitor and report unusually large or frequent orders for the opioids. The Distributor Defendants turned a blind eye to the dangerous diversion of opioid medication into and throughout Jefferson County, West Virginia.

286. The combined actions and inactions of the Manufacturer and Distributor Defendants is a direct and proximate cause of the opioid epidemic – including the illegal heroin epidemic – currently plaguing Jefferson County.

287. The sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States. Scientific evidence demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled and their abuse.[102]

288. Defendants continue to obfuscate the manifest link between detailing and access to opioids. Contrary to Defendants' misrepresentations, most of the illicit use stems from **prescribed** opioids; in 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.[103] According to the CDS, the 80% of opioid patients who take low-dose opioids from a single prescriber (in other words, who are not illicit users or "doctor-shoppers") account for

[102] Theodore J. Cicero et al., *Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States,* (16)8 Pharmacoepidemiologyand Drug Safety, 827-840 (Aug. 2007).
[103] *Results from the 2011 Nat'l Survey on Drug Use & Health: Summary of Nat'l Findings,* U.S. Dep't of Health & Human Services (Sept. 2012), http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.pdf.

20% of all prescription drug overdoses.[104] In 2009, there were more than twice as many deaths from prescription opioid overdoses (15,597) than from cocaine (4,350) and heroin (3,278) put together.

289. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are 40 more likely to be addicted to heroin.[105]

290. Heroin is pharmacologically like prescription opioids. Most current heroin users report having used prescription opioids nonmedically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.[106]

291. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. **Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use,** specifically among users who report past-year dependence or abuse. The increased availability of heroin, combined with its

[104] *CDC Grand Rounds: prescription Drug Overdoses, a U.S. Epidemic*, Centers for Disease Control & Prevention (Jan. 13, 2012), www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.html.
[105] *See* CDC Vital Signs Fact Sheet, *Today's Heroin Epidemic*, U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention (July 2015).
[106] *See* Wilson M. Compton, MPE, *Relationship between Nonmedical Prescription Opioid Use and Heroin Use*, New Eng. J. Med., 374:154-163 (January 14, 2016).

relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.[107]

292. Fundamentally, prescription opioids and heroin are elements of a larger epidemic of opioid related disorders and death. Viewing them from a unified perspective is essential to improving public health. The perniciousness of this epidemic requires a multipronged interventional approach that engages all sectors of society.[108]

293. Opioid analgesics are misrepresented, widely diverted, and frequently improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addiction.[109] The increased use of prescription painkillers for nonmedical reasons (without a prescription for the high they cause), along with growing sales, has contributed to a large number of overdoses and deaths.[110] There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.[111]

294. The public health dangers associated with the diversion and abuse of controlled prescription drugs have been well recognized over the years by Congress,

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[107] *See* Rose A. Rudd, MSPH, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000 – 2014*, Morbidity and Mortality Weekly Report ("MMWR"), Centers for Disease Control and Prevention, 64(50; 138-82 (January 1, 2016).
[108] *See* Compton, *Relationship between Nonmedical Prescription Opioid Use and Heroin Use*.
[109] *See* Nora D. Volkow and A. Thomas McLellan, Ph.D., *Opioid Abuse in Chronic Pain*, New Eng. J. Med., 374:1253-63 (March 31, 2016).
[110] *See* Press Release, *Prescription painkiller overdoses at epidemic levels*, U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention (November 1, 2011).
[111] *See* Richard C. Dart, MD, et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Eng. J. Med., 372:241-248 (January 15, 2015).

DEA, HDMA, and NACDS and its members, and public health authorities.[112] Opioids are involved in 40% of fatal drug overdoses – including overdoses due to illegal drugs.[113] But death statistics represent only the tip of the iceberg.

295. Infants and children have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioid due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS"). These infants painfully withdraw from the drug once they are born. They cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction.[114] When untreated, NAS can be life-threatening.[115] In 2009, More than 13,000 infants in the United States were born with NAS, about one every hour.[116]

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[112] *See* Brief for HDMA and NACDS, 4, *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*
[113] Margaret Warner et al., *NCHS Data Brief: Increase in Fatal Poisonings Involving Opioid Analgesics in the United States, 1999-2006,* Centers for Disease Control & prevention (Sept. 2009), www.cdc.gov/nchs/data/databriefs/db22.pdf.
[114] *Transcript of Impact of Approved Drug Labeling – Part 15 Hearing* at 116-121, F.D.A. (Feb. 7, 2013), www.fda.gov/downloads/Drugs/NewsEvents/UCM342700.pdf.
[115] *See*, Letter from Janet Woodcock, Dir., FDA Ctr. For Drug Evaluation & Research, to Petitioner, Nat'l Advocates for Pregnant Women (Apr. 16, 2014).
[116] Stephen W. Patrick et al., *Neonatal Abstinence Syndrome& Associated Health Care Expenditures,* 307(18) Journal of the Am. Med. Ass'n 1934, 1937 (May 9, 2012

296. Further, the overprescription and diversion of opioids for chronic non-cancer pain has given young children access to opioids, nearly all of which were prescribed for adult in their household. One study documented over 9,000 children nationally exposed to prescription opioids with a median age of two years old. The number of exposures in young children was correlated to the number of prescriptions in the area.[117]

B. By creating and perpetuating the opioid epidemic, the Manufacturer and Distributor Defendants have caused severe damage to Jefferson County . . .

297. From the time prescription opioids became widely available in the mid-1990's to today, the number of Americans using – and abusing – the drugs has exploded. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[118]

298. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or an emergency department have increased by a factor of six in the past 15 years.[119]

299. West Virginia has the highest rate of drug overdose deaths in the United States. West Virginia had 36.3 drug overdose deaths per 100,000 people in 2011, nearly

[117] J. Elise Baily et al., *The under-recognized toll of prescription opioid abuse on young children*, 53(4) Annals of Emergency Med., 419-424 (Apr. 2009).
[118] *See* Katherine M. Keyes, Ph.D. et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, Amer. J. Pub. Health, Vol. 104 No.2, e52-e59 (February 2014).
[119] *See* Volkow, *Opioid Abuse in Chronic Pain*.

triple the U.S. rate (13.2/100,00). Prescription drugs – opioids and benzodiazepines in particular – are major drivers of the drug overdose deaths in West Virginia. Opioid-prescribing rates in West Virginia are among the highest in the country. In 2012, West Virginia providers wrote 137.6 opioid pain reliever prescriptions per 100 people, the third highest prescribing rate in the country and far above the U.S. rate (82.5/100).[120]

300. In 2014, West Virginia had the highest drug overdose death rate in the United States (35.5 deaths per 100,000 people). In 2015, the state again had the dubious honor of having the highest drug overdose death rate in the United States (41.5 deaths per 100,000 people).

301. West Virginia leads the nation in opioid deaths and has a drug addiction problem that is devastating families and communities across the state.[121] The societal costs of prescription drug abuse are huge.

302. Jefferson County is on the frontline of the prescription opiate and heroin epidemic. According to data drawn from Vital Statistics from the National Center for Health Statistics (NCHS), in 2014, the United States experienced a drug poisoning death rate of 14.8 (per 100,000 population, West Virginia experienced a drug poisoning rate of 34.7 (per 100,000 population) and **Jefferson County experienced a drug poisoning rate with a range of 20.1 - 22 (per 100,000 population). The drug poisoning death**

[120] *See* Press Release, Centers for Disease Control and Prevention, *"CDC awards over $1 Million to West Virginia to address prescription drug overdose prevention"* (August 14, 2014).
[121] *See* Correspondence from Louise Reese, CEO, West Virginia Primary Care Association to WVAC Patrick Morrissey (August 9, 2016).

rate in Jefferson County has consistently exceeded the national average during the prescription opiate epidemic:

Year	United States	Jefferson County
2010	12.5	14.1 - 16
2011	13.4	16.1 – 18
2012	13.3	16.1 - 18
2013	14	18.1 – 20

303. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effect on opioid addiction treatment while safely meeting the needs of patients experiencing pain.[122] To eliminate the hazard to public health and safety, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[123] These community-based problems require community-based solutions which have been limited by "budgetary constraints at the state and Federal levels."[124]

304. Plaintiff Jefferson County Commission seeks to eliminate such budgetary constraints by holding the Manufacturer and Distributor Defendants financially responsible for the economic costs of eliminating the hazards to public health and safety and abating the temporary public nuisance caused by the unlawful conduct recited herein.

[122] *See* Rudd, *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015.*
[123] *Id.*
[124] *See* Barack Obama, President of the United States, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011).

VII. CAUSES OF ACTION

COUNT ONE
Public Nuisance

305. Plaintiff incorporates herein all allegations above.

306. Plaintiff JEFFERSON COUNTY COMMISSION alleges a public nuisance action consistent with that alleged in *Hark v. Mountain Fork Lumber Co.*, 127 W. Va. 586, 595-96, 34 S.E.2d 348, 354 (1945).

307. A public nuisance is an unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive to community moral standards, or unlawfully obstructing the public in the free use of public property.

308. Defendants intentionally, unlawfully, and recklessly advertise, sell, and distribute prescription opioids in Jefferson County, resulting in the fact that prescription opiate abuse, addiction, morbidity, and mortality are a public nuisance in Jefferson County, West Virginia.

309. The Manufacturer Defendants knew and should have known that their promotion of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of a public nuisance.

310. The Distributor Defendants knew and should have known that their over-distribution of opioids into Jefferson County and their refusal and failure to prevent the diversion of opioids into and throughout Jefferson County would create or assist in the creation of a public nuisance.

311. Defendants' conduct significantly interfered, and continues to significantly interfere with the public health and safety, the public peace, and the public comfort.

312. Defendants' had control over that conduct in Jefferson County and that conduct had an adverse effect on the public right. The public nuisance has significantly harmed a considerable number of the County's residents. The continued tortious conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once, but have increased as time progresses. The tort is not completed, nor have all the damages been incurred, until the wrongdoing ceases. The wrongdoing has not ceased. The public nuisance remains unabated. *Rhodes v. E.I. du Pont de Nemours & Co.*, 657 F.Supp.2d, 752, 760 (S.D. W. Va. 2009), *aff'd in part, appeal dismissed in part,* 636 F.3d 88 (4th Cir. 2011).

313. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic and state of emergency described in the complaint, and that harm outweighs any offsetting benefits.

314. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety, or comfort of a considerable number of persons in Jefferson County by their production, promotion, marketing, distribution, and sale of opioids for use by residents of Jefferson County.

315. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used, in deceiving healthcare professionals and patients about the risks and benefits of opioids for the treatment of chronic pain, the

enormous volume of opioids that flooded the County, and in the public health crisis that has followed.

316. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

317. Defendants' conduct in marketing, distributing, and selling prescription opioids which the Defendants know, or reasonably should know will likely be diverted for non-legitimate, non-medical use creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to Jefferson County residents and otherwise significantly and unreasonably interfere with public health, safety, and welfare, and with the public' right to be free from disturbance and reasonable apprehension of danger to person or property.

318. It is, or should be, reasonably foreseeable to Defendants that their conduct will cause deaths and injuries to Jefferson County residents, and will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

319. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Jefferson County not only causes deaths and injuries, but also creates a palpable climate of fear among Jefferson County residents where opioid abuse, diversion, and addiction are prevalent and where they tend to be used frequently.

320. Defendants' conduct makes it easier for persons to divert prescription opioids constituting a dangerous threat to the public.

321. The nuisance created, perpetuated, and maintained by the Defendants can be abated and further recurrence of the harm and inconvenience can be abated.

322. Stemming the misleading, unsupported, marketing of prescription opioids and stemming the flow of illegally distributed prescription opioids into Jefferson County will help to alleviate the opioid epidemic and the associated threat to the health and safety of this County.

323. Jefferson County has been, and continues to be, directly and proximately injured by Defendants' actions in creating a public nuisance.

324. Plaintiff JEFFERSON COUNTY COMMISSION seeks non-economic damages from the Defendants as just compensation for annoyance, discomfort, and inconvenience caused by the public nuisance. Syl. Pt. 3, *Taylor v. Culloden Pub. Serv. Dist.*, 214 W. Va. 639, 591 S.E.2d 197 (2003).

325. The JEFFERSON COUNTY COMMISION is "authorized to enact ordinances, issue orders, and take other appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-1(a).

326. Plaintiff JEFFERSON COUNTY COMMISSION seeks punitive damages to deter the Defendants and others from committing like offenses in the future. *Hensley v. Erie Ins. Co.*, 168 W. Va. 172, 183, 283 S.E.2d 227, 233 (1981).

327. Redress of the wrong to the entire community is left to its duly appointed representatives, in this case, the JEFFERSON COUNTY COMMISSION. *See* Restatement (Second) of Torts § 821C (1979).

COUNT TWO
COMMON LAW NEGLIGENCE

328. Plaintiff incorporates herein all allegations above.

329. For negligence to be actionable, "[t]he plaintiff must prove that the defendant[s] owed the plaintiff some duty of care, that by some act or omission the defendant breached that duty; and that the act or omission proximately caused some injury to the plaintiff that is compensable by damages." *Hersh v. E-T Enterprises, Ltd. P'ship*, 232 W. Va. 305, 310, 752 S.E.2d 336, 341 (2014). Each of these essential elements exist in this case.

330. Here, each Manufacturer Defendant had a duty to exercise due care in advertising and promoting its dangerous opioid drugs. Each Distributor Defendant had a duty to exercise due care in distributing highly dangerous opioid drugs in Jefferson County.

331. The existence of a duty depends on the foreseeability of the injury. *Louk v. Isuzu Motors*, 198 W. Va. 250, 260, 479 S.E.2d 911, 921 (1996). Each Defendant owed a duty to Jefferson County and to the public health and safety in Jefferson County, because the injury was foreseeable, and in fact, foreseen by the Defendants.

332. Reasonably prudent drug manufacturers and distributors would have anticipated that the scourge of opioid addiction would wreak havoc on communities. As

outlined above, the federal regulations governing the manufacture, advertising, labeling, distribution and sale of opioid drugs exist **for the express purpose** of controlling dangerous substances. Moreover, Defendants were repeatedly warned by law enforcement.. The escalating amounts of addictive drugs flowing from the Manufacturer Defendants and through the Distributor Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

333. As described above in language expressly incorporated herein, Defendant each breached their duties to exercise due care in the business of manufacturing and distributing dangerous opioids, which are Schedule II Controlled Substances, by misleadingly promoting and advertising prescription opioids; funding, supporting, and encouraging misleading and incomplete studies of prescription opioids; filling highly suspicious orders of prescription opioids again and again. Because the very purpose of the Manufacturer and Distributor Defendants' duties was to prevent the resulting harm, the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

334. As described above in language expressly incorporated herein, Defendants' breach of duty caused, bears a causal connection with, and/or proximately resulted in, harm and damages to Jefferson County.

335. Defendants acted with actual malice.

336. Plaintiff JEFFERSON COUNTY COMMISSION seeks all legal and equitable relief as allowed by law, including inter alia injunctive relief, restitution,

disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT THREE
Fraud and Intentional Misrepresentation (Manufacturer Defendants)

337. Plaintiff herein incorporates all allegations above.

338. Defendants, individually and acting through their employees and their agents, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

339. In overstating the benefits of and evidence for the use of opioids for chronic pain and understand their very serious risks, including the risk of addiction; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, including in Jefferson County, Defendants have engaged in misrepresentations and knowing omissions of material fact.

340. Specifically, misrepresentations or omissions include, but are not limited to:

a) Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b) Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with even more opioids;

c) Defendants' claims that screening tools effectively prevent addiction;

d) Defendants' claims that opioid doses can be increased until pain relief is achieved;

e) Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f) Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g) Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h) Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

i) Purdue's claims that OxyContin provides a full 12 h ours of pain relief; and

j) Purdue's and Endo's claims that they cooperate with and support efforts to prevent opioid abuse and diversion.

341. By engaging in the acts and practices alleged herein, Defendants omitted to state material facts that it had a duty to disclose by virtue of Defendants' other representation, including, but not limited to, the following:

a) opioids are highly addictive and may result in overdose or death;

b) no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c) high dose opioids subject the user to greater risks of addiction, other injury, or death;

d) exaggerating the risks of competing products, such as NSAIDS, while ignoring the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines;

e) Defendants' claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f) Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g) Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease, and may increase overall abuse; and

h) Purdue and Endo failed to report suspicious prescribers.

342. Defendants' statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence, as confirmed by the CDC and FDA.

343. Further, Defendants omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and were likely to mislead City prescribers and consumers when taken in the context of the surrounding circumstances.

344. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

345. Defendants intended that the City and its residents would rely on their misrepresentations and omissions.

346. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, the City suffered actual pecuniary damage.

347. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

348. Plaintiff JEFFERSON COUNTY COMMISSION seeks all legal and equitable relief as allowed by law, including inter alia injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT FOUR
Racketeer Influenced and Corrupt Organizations Act ("RICO")
18 U.S.C. §§ 1961 *et seq*.

349. Plaintiff incorporates herein all allegations above.

350. Each Defendant is associated with an enterprise which affects interstate commerce for purposes which include the illegal distribution of opioids. As explained herein, each Defendant conducted or participated in the enterprise's affairs through commission of criminal offenses which constitute a pattern of racketeering activity. *See In re ClassicStar Mare Lease Litig.*, 727 F.3d 473, 483-494 (6th Cir. 2013). Defendant coprorations are "persons" within the meaning of 18 U.S.C. § 1961(3) which conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962. *In re ClassicStar Mare Lease Litig.*, 727 F.3d at 490-494.

351. The Plaintiff was injured in its business or property as a result of each Defendant's wrongful conduct and is a "person" who can bring an action for violation of section 1962, as that term is defined in 18 U.S.C. § 1961(3). "Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefore in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee . . ." 18 U.S.C. § 1964; *see also City of Cleveland v. Woodhill Supply, Inc.*, 403 F. Supp.2d 631 (N.D. Ohio 2005) ("municipal corporation was "person" with standing to bring a RICO claim).

A. The Opioids Diversion Enterprise

352. Each Defendant formed an association-in-fact enterprise ("Opioids Diversion Enterprise") and participated in the affairs of this enterprise when distributing highly dangerous, addictive opioid drugs in Jefferson County. Each Defendant's Opioid Diversion Enterprise consists of (a) each Manufacturer Defendant, including its employees and agents; (b) each Distributor Defendant, including its employees and agents; and (c) each Distributor Defendant's retail pharmacies, which placed orders for vast quantities of opioids. Indeed, the Defendants could not have diverted opioids without the participation of retail pharmacies. The events described herein required retail pharmacies to place orders for these vast quantities of opioids.

353. Each Manufacturer Defendant participated in the conduct of the Opioids Diversion Enterprise, sharing the common purpose of profiting from the sale of opioids, through a pattern of racketeering activity, by offering economic incentives meant to

entice the Distributor Defendants to push a volume of opioid medications to retail pharmacies with no regard for the probability of diversion of opioids. The Manufacturer Defendants conducted these activities in violation of West Virginia law and multiple instances of wire or mail fraud.

354. Each Distributor Defendant and its respective pharmacy customers participated in the conduct of the Opioids Diversion Enterprise, sharing the common purpose of profiting from the sale of opioids, through a pattern of racketeering activity, which includes multiple violations of West Virginia state criminal law and multiple instances of mail or wire fraud.

355. Each Defendant's Opioids Diversion Enterprise is an ongoing and continuing business organization that created and maintained systematic links for a common purpose: to profit from the sale of opioid prescription pills. Each Manufacturer Defendant conducted this enterprise by flagrantly committing mail fraud through false advertisement and claims. Each Distributor Defendant conducted this enterprise notwithstanding that its failure to abide by mandatory checks and balances constituted unlawful diversion of a dangerous controlled substance.

356. The system is structured so that wholesalers and pharmacies see greater profits at higher volumes. As a result, these companies are financially discouraged from undertaking efforts to combat opioid abuse. Wholesale Distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost ("WAC"). Discounts and rebates may be offered by the manufacturers based on market share and volume. Thus, the Manufacturer Defendants incentivized the

Distributor Defendants to order greater amounts of opioids so that they can decrease the cost per pill. The Distributor Defendants then used the decreased cost per pill to increase their market share (and thus, profits) by offering more competitive prices, or they maintained their prices and pocketed the difference as additional profit. Either way, sales volumes increased for all Defendants.

357. As described above and expressly incorporated herein, the Defendants were placed on notice by the FDA and the DEA, and were the subject of repeated FDA and DEA enforcement action. Still the Defendants continued to misrepresent their compliance with their legal obligations to maintain a closed system of opioid distribution.

358. Each Defendant's Opioid Diversion Enterprise has caused opioids to be avused throughout JEFFERSON County, with an ongoing cascade of human suffering and death that continues to consume the resources of the County's health and human services, health care, and law enforcement systems.

359. Each Defendant and the respective retail pharmacy customers were willing participants in the Opioids Diversion Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

B. Conduct of the Opioids Diversion Enterprise

360. To accomplish the common purpose of profiting from the sale of opioid prescription pills, each of the Manufacturer Defendants' Opioids Diversion Enterprise periodically and knowingly distributed false scientific and advertising material to doctors

and consumers in Jefferson County in order to create a market for opioid medication to treat chronic noncancer pain.

361. To accomplish the common purpose of profiting from the sale of opioid prescription pills each of the Distributor Defendants' Opioids Diversion Enterprise periodically and systematically misrepresented – either affirmatively or through half-truths and omissions – to the general public, the JEFFERSON COUNTY COMMISSION, Jefferson County Consumers, and the West Virginia Board of Pharmacy, that it was fulfilling the requirements of its West Virginia wholesale distributor license when, in fact, the duty to maintain effective controls to prevent diversion for non-medical purposes was being ignored in pursuit of ever increasing profits.

362. The persons engaged in each Defendant's Opioids Diversion Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities. Typically, this communication occurred, and continues to occur, through the use of the wires and mail in which each Manufacturer Defendant and Distributor Defendant communicate to facilitate the wholesale of massive amounts of opioid pills, and then each Distributor Defendant and its respective retail pharmacy customers communicate to facilitate the prescription opioid orders.

363. Each Defendant's Opioids Diversion Enterprise functions as continuing unit for the purposes of profiting from the sale of opioid prescription drugs.

364. At all relevant times, the retail pharmacy customers were aware of the Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct.

365. The sheer volume of prescription opioids flowing from the Manufacturer Defendants to the Distributor Defendants and from the Distributor Defendants and into communities across the country, including Jefferson County, shocks the conscience and required each Defendant to take appropriate action, such as investigating and reporting the frequent, large orders as suspicious.

366. Further, given their place in the closed supply chain, the Distributor Defendants are uniquely situated to identify suspicious transactions within a community. However, determined to increase their revenues, each of the Distributor Defendants willfully ignored obvious warning signs concerning suspicious orders. It would be virtually impossible for all of the orders to be legitimate, as there was no medical-need correlation justifying the skyrocketing orders for these addictive drugs.

367. For all times relevant to this Complaint, each Defendant exerted control over its Opioids Diversion Enterprise, and participated in the operation and management of the affairs of the Opioids Diversion Enterprise, directly or indirectly, in the following ways:

a) To facilitate the increased profits of all parties involved, the Manufacturer Defendants created markets for their opioids by committing fraud and disseminating information that is false, misleading, imbalanced and unsupported by science;

b) The Distributor Defendants obtained licenses from the West Virginia Board of Pharmacy but, contrary to the requirements of federal and West Virginia law, Defendants failed to take necessary action to maintain effective controls against diversion of dangerously addictive prescription opioids, and in dereliction of non-delegable duties, sold opioid pills to their retail pharmacy customers notwithstanding that the increase and quantum of addictive drug orders raised serious red flags regarding the drugs' unlawful, non-medical use;

c) Defendants each misrepresented their compliance with their legal obligations, making false assurances that their distribution complied with the law, including without limitation in the case of the Distributor Defendants the requirements of a West Virginia distributor license, when, in truth, Defendants sold all the opioids they could, for profit, and in violation of their legal duties to guard against diversion of prescription opioids for illicit purposes;

d) Defendants refused to heed the DEA's warnings and continued to sell opioids and fill suspicious orders which were likely to be diverted;

e) Defendants refused to abide by the terms of DEA enforcement actions and settlements, continuing to sell opioids to fill suspicious orders;

f) Defendants did not monitor, detect, investigate, refuse to fill, and report suspicious orders to the West Virginia Board of Pharmacy as required under the terms of their licenses and applicable law;

g) Defendants intentionally and/or unlawfully sold the opioids unlawfully, purely for profit and without regard to the opioid plague, notwithstanding Defendants' knowledge that substantial foreseeable harm would occur; and

h) Defendants only succeeded in these opioid sales by using wire and mail to communicate with one another, and the Distributor Defendants used wire and mail to communicate with the retail pharmacies.

368. The Manufacture Defendants conducted business with the Distributor Defendants via mail and wire. The Distributor Defendants employed mail and wire to order opioids from the Manufacturer Defendants. The retail pharmacies participated in each Defendant's Opioid Diversion Enterprise by employing mail and wire to send orders of opioids to the Distributor Defendants and to buy opioids from the Distributor Defendants.

369. The scheme devised and implemented by each Defendant, as well as the other members of each Defendant's Opioids Diversion Enterprise, amounted to a common course of conduct intended to result in profits from opioid sales.

C. Pattern of Racketeering Activity

370. Defendants conducted and participated in the conduct of the affairs of their respective Opioids Diversion Enterprise through a pattern of racketeering activity, which constitutes corrupt activity, which violates 18 U.S.C. § 1962(c).

371. Regardless of any licenses or registrations held by Defendants to distribute dangerous and harmful drugs, their conduct was not "lawful." Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

372. The pattern of racketeering activity alleged herein and each Defendant's Opioids Diversion Enterprise are separate and distinct from each other. Likewise each Defendant is distinct from its respective Opioids Diversion Enterprise.

373. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

374. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, Defendants misrepresentation to the public, the FDA, the West Virginia Board of Pharmacy, and the DEA depended on secrecy.

375. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including the County and its citizens. Each Defendant crafted its scheme to ensure its own profits remained high, without regard to the effect such behavior had on the County and its citizens. In designing and implementing their respective schemes, at all times each Defendant was cognizant of the fact that those in the distribution chain and the West Virginia Board of Pharmacy and DEA rely on the integrity of the manufacturers and the wholesale distributors to maintain a closed system and to protect against the non-medical uses of these dangerously addictive opioid drugs.

376. Each Defendant knowingly engaged in, attempted to engage in, conspired to engage in, or solicited another person to engage in racketeering activity, including the

distribution of dangerous and harmful drugs to persons, including minors, in violation of West Virginia law, at retail pharmacies, hospitals, and other health care facilities throughout Jefferson County.

377. Defendants' actions were criminal and in violation of W.Va Code 60A-4-401(a) which forbids any person or entity not authorized under West Virginia law from providing another with a controlled substance which causes physical harm or dependency and the distribution of controlled substances. The statute states that it is a felony for any person to manufacture, deliver, or poses with intent to manufacture or deliver a controlled substance classified in Schedule 1 through IV. This felony carries a penalty of greater than one year.

378. Although the Distributor Defendants may have been registered and licensed with the West Virginia Board of Pharmacy, they were not acting in accordance with their license, because they failed to inform the Board of Pharmacy of any suspicious orders.

379. Each Defendant knowingly engaged in, attempted to engage in, conspired to engage in, or solicited another person to engage in racketeering activity, including thousands of separate instances of use of the United States Mail or interstate wire facilities in furtherance of each Defendant's unlawful Opioids Diversion Enterprise. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity. Each Defendant specifically intended to obtain money by means of false pretenses, representations, and promises, and used the mail and interstate wires for the purpose of executing this scheme; specifically, each Defendant communicated with its

respective customers via wire and use the mail to receive order and sell drugs unlawfully. Any violation of the mail or wire fraud statutes is defined as "racketeering activity." 18 U.S.C. § 1961(1)(B).

D. Damages

380. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused the County and its citizens to be injured in their business or property because the JEFFERSON COUNTY COMMISSION has paid for costs associated with the opioid epidemic, as described above and expressly incorporated herein by reference.

381. The County's injuries, and those of her citizens, were directly caused by Defendants' racketeering activities.

382. The County was most directly harmed, and there is no other Plaintiff better situated to seek a remedy for the economic harms at issue here.

383. Plaintiff JEFFERSON COUNTY COMMISSION seeks all legal and equitable relief as allowed by law, including actual damages, treble damages, equitable relief, a civil penalty of up to one hundred thousand dollars, attorney fees and costs, and pre- and post-judgment interest.

COUNT FIVE
Unjust Enrichment

384. Plaintiff herein incorporates all allegations above.

385. Defendants have unjustly retained a benefit to the detriment of JEFFERSON COUNTY COMMISSION, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

386. By illegally and deceptively promoting opioids, Defendants have unjustly enriched themselves at the JEFFERSON COUNTY COMMISSION'S expense. The City has made payments for opioid prescriptions and treatments, and Defendants benefited from those payments. Because of their deceptive promotion of opioids, Defendants obtained enrichment they would not have obtained. The enrichment was without justification and the JEFFERSON COUNTY COMMISSION lacks a remedy provided by law.

387. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged in substantial amount to be determined at trial.

COUNT SIX
Civil Conspiracy

388. Plaintiff herein realleges all allegations above.

389. Defendants knowingly and voluntarily participated in a common scheme to commit unlawful acts or lawful acts in an unlawful manner.

390. The Manufacturer Defendants common scheme was carried out through their common funding of the same front groups, CME's and KOLs, their common advocacy, their coordinated marketing messages, their coordinated failure to report.

391. The defendants participated in unlawful acts in an unlawful manner as described above.

392. By reason of the Defendants' unlawful acts, Jefferson County has been damaged and continues to be damaged, not least by its payments for costs associated with the opioid epidemic, as described above and expressly incorporated herein by reference.

VIII. PRAYER FOR RELIEF

WHEREFORE, the JEFFERSON COUNTY COMMISSION requests the following relief:

393. A finding that by the acts alleged herein, the Defendants have created a public nuisance;

394. An award of three times the Plaintiff's actual damages under 18 U.S.C. § 1964;

395. An injunction permanently enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with them from engaging in the acts and practices that caused the public nuisance;

396. An award of damages caused by the opioid epidemic, including without limitation (A) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments/services for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (B) costs for providing treatment, counseling, rehabilitation services; (C) costs for providing treatment of infants born with opioid related-medical conditions; (D) costs associated with law enforcement and public safety relating to the opioid epidemic; and (F) any other expenses or damages caused by the Defendants' diversion of opioids;

397. An Order directing the Defendants to abate and pay past and future costs of abating the ongoing public nuisance caused by the opioid epidemic;

398. Order Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance;

399. Compensatory and punitive damages for the Defendants' fraud and negligent misrepresentation;

400. Restitution or disgorgement of the Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

401. Court costs and reasonable attorney's fees;

402. Pre-judgment and post-judgment interest; and

403. For all other relief deemed just by the court.

JEFFERSON COUNTY COMMISSION
By Counsel

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